Appendix D
HTRW Technical Project Planning Process

D.1 Introduction

The USACE recognizes the need for cost-effective and efficient %/response actions for HTRW projects. The level of effort required in conjunction with the data collection activities for a HTRW project are based on DQOs which address data quality and quantity requirements of the users. The recently published Engineer Manual, Tech***nical Project Planning - Guidance for HTRW Data Quality Design*** (USACE 1995b) (EM 200-1-2) [referred to ***as the*** HTRW ***Technical Project Planning Guidance in*** this appendix] provides project planning guidance to develop data collection programs and define DQOs for HTRW sites. This appendix summarizes the four phases of the HTRW technical project planning - data quality design process with respect to scoping requirements and data needs for conducting ERAS to support risk management decisions.

The importance of early planning and getting the risk assessor involved in the planning process at each phase of the HTRW response action is emphasized so that data needed to assess potential ecological risks will be cost-effectively collected. In identifying data needs for the ERA, the risk assessor must fully understand the customer goals, regulatory programs driving the HTRW project execution and the associated project decision statements (PDs), the study elements for each relevant project phase, and the types of ERA needed by the study elements. An ECSM should be developed and used to focus data needs to evaluate risks for complete exposure pathways to significant ecological receptors or for the ecosystem to be protected. In addition, it is important to simultaneously consider the data needs for both the ERA and the human health assessment throughout the HTRW planning program. Both assessment processes will have some data needs in common which should be identified so that dup lication of effort is avoided.

This appendix is divided into the following sections:

- Introduction - This section presents the scope and introductory statements.
- Overview of the HTRW Technical Project Planning Process - This section summarizes the four-phases (Phase I through Phase IV) of the data quality design process.
- Roles and Responsibilities - This section describes the roles and responsibilities of the risk assessor in the data quality design process. In addition, how this individual uses the skills and experience of the expert ecologist(s) and/or the advisory panel such as the BTAG to focus the approach and the data needs to support site decisions is described.
- Data Needs for HTRW Executable Project Phases - This section presents a framework for conceptualizing data needs, establishing data requirements, and the basis for requiring such data. Conceptualizing and establishing the rationale for data use and data needs are critical elements of the Phase II data quality design process. This section addresses key executable project phases (i.e., PA/SI and RFA; RI and RFI; FS and CMS; and RD/RA and CMI)
- Summary Conclusions - This section summarizes the role and responsibility of a risk assessor in the four-phased HTRW data quality design process, along with general data needs and study elements to support making site decisions in each executable phase of the HTRW project.

D.2 Overview of the HTRW Technical Project Planning Process

The key to the HTRW technical project planning process for a response action is understanding the customer's needs and the regulatory requirements/basis for making site decisions. Designing the data collection strategy requires professional judgment, scientific decisions, regulatory policy, and the customer's goals, to which no single person including the data implementor, can easily

develop a data acquisition strategy to satisfy all users' needs.

The project planning process at various stages requires the involvement of appropriate project personnel which consist of:

- Decision makers (customer, PM, TM).
- Data users (risk assessors, remedial design engineers, compliance specialists, and responsibility-specialists or legal counselors for identifying potentially responsible parties [PRPs]).
- Data implementors and reviewers (statistician, sampling specialists [e.g., geologists, hydrogeologists, meteorologists, and biologists], analytical specialists [chemists], the health and safety officer, etc.).

The primary products of this data quality design process are the Scope of Work, DQO statements for use in the Sampling and Analysis Plan (SAP), and detailed estimates of costs associated with the selected data collection program. Other uses for the above outputs could be to form the basis for developing specific language of or as excerpts from: the FFA/IAG under CERCLA or the FFCA under RCRA; Department of Defense and State memorandum of understanding (DSMOA); and the Project Management Plan (PMP), etc.

[1] For example, the risk assessor has recommended taking sediment samples in a swale or runoff channel originating from a PCB spill area to evaluate the potential risks to wetland receptors. The statistician has recommended using a grid design with systematic random sampling to determine where sediment samples are to be collected from the swale. However, a decision has to be made on the grid size, which is dependent on the variability of PCB concentrations in previously collected sediment samples and the acceptable error rate or level of confidence for not being able to detect a hot spot. Therefore, designing the sampling program represents a joint effort of the Technical Planning Team members. The use of previously collected sediment data and setting a predetermined confidence level will involve a management decision by the PM/regulator and the USACE customer. Input from the risk assessor and statistician include both professional judgment and scientific decisions (i.e., delineation of the exposure unit [Eu] or study area, concern levels to be detected, sampling depth based on potential exposure pathways for valued receptors to be protected, and the concept of systematic random sampling).

D.2.1 Phase 1 - Develop Project Strategy

Phase I of the technical project planning process involves understanding the customer's objectives and requirements for making site decisions, and putting together a logical approach which addresses the questions to be answered or the decisions needed for specific project phases.

In terms of project execution from site discovery to close-out, key inputs required for decision-making can be more readily defined after site-specific conditions are generally understood, and the action plan/strategy is developed. A strategy may be defined as the approach by which actions and resources are organized, targeted, and used in order to fulfill a mission or meet certain objectives or policies. For example, after having a general understanding of the release, migration, and transport properties of the COECs, the ecological assessment component of the strategy for a typical CERCLA or RCRA site could be: (1) identify if sensitive species or valued resources (receptors) exist onsite or in the site vicinity; (2) if such receptors exist, collect chemical data to identify the boundary of the area of ecological concern; (3) ascertain if receptors are located within the boundary: (4) recommend no further action if the response to item (1) or (3) is negative; (5) compare chemical data with literature or benchmark (screening) values for the receptors or surrogate species if the response to items (1) and (3) is positive: (6) further assess the site at the population or community level to determine the significance of the potential ecological impact if the screening levels or literature values in item (5) have been exceeded, and (7) implement removal, remedial, or corrective action if the ecological risk determined in (5) and/or (6) is judged to be significant

Before development of the site strategy, certain site information should be gathered for review by the technical project team. Such information includes, but is not limited to, regulatory or compliance requirements; previously collected chemical or nonchemical data; history of operations: documented incidents or corroborated reports of ecological concern (e.g., animal mortality/morbidity, anatomical or pathological anomalies in aquatic or terrestrial receptors, etc.); and information obtained from the PA/site reconnaissance. In addition, before development of an overall site strategy in Phase I, the following project management information should be obtained:

- Customer's goals and meaning or concept of site closeout to focus and define site problem(s).
- Customer's budget and schedule constraints.
- Primary and secondary regulatory pro rams under which the HTRW project is executed.[2]
- The stages or project phases under the above regulatory programs (i.e., project phase on the critical path [decision-tree] for actions).
- Stressors (COECs or nonchemical entities), existing or potential exposure pathways, known or suspected ecological effects from the COECs/ nonchemical entities, and endpoints (i.e., value of resources to be protected) relevant to the customer's objectives or concern.
- OUs, SWMUs, CAMUs, temporary units, areas of contamination, etc., and potential exposure units (EUs) or the boundary of ecological concern.
- Reasonably anticipated future land uses of the site (which are needed to conceptualize exposures to ecological receptors under future exposure scenarios).
- Anticipated remedies (including removal actions, interim measures, presumptive remedies, and innovative technologies, if feasible).
- Objectives and scope of all possible executable phases from the current project phase to site closeout.

Based on the above information, the customer and technical planning team members may consult with the relevant expert ecologist(s) or advisory panel (e.g., BTAG) before finalizing (or determining) the overall site strategy ***or*** the strategy for the current project phase.

The following activities will be critical for a successful implementation of the site strategy:

- Identify site Constraints and Dependencies (i.e., Work Breakdown Structure [WBS]; product milestones: level and duration of efforts: availability and timing of funding: technical limitations or requirements; and regulatory deadlines).
- Develop potential options, as appropriate, for achieving site closeout (e.g., removal or accelerated cleanup, phasing [in series or parallel], or no further action/monitoring only).
- Decide on the executable phase and choose or assemble project decision statements (PDs) specific for the phase, focusing on the critical path and needs for data inputs.
- Develop a preliminary ECSM or update an existing ECSM to help meet project objectives and data needs.
- Finalize USACE Acquisition Strategy to perform work, issue a preliminary Scope of Work (an outline for the Statement of Work), and/or develop a Site Summary/I'M Memo, which incorporates all of the above.

The key output for Phase I is preparation of a Scope of Work Outline and/or TM memorandum which identifies the customer's goals and the concept of site closeout,

[2] There are currently unresolved RCRA/CERCLA integration issues which concern administrative, statutory, and jurisdictional overlap. For example, a Federal facility that is listed or proposed on the NPL may have interim status or may be a permitted facility under RCRA. Alternatively, it is possible that releases from a RCRA regulated unit caused the NPL listing. In these cases, the questions that follow would be Which statute should be used as the primary vehicle to require cleanup, if cleanup is needed?" and "Which agencies (EPA and/or State) should oversee the investigation and cleanup?" In certain instances, it is possible that a Natural Resource Damage Assessment (NRDA) may be required by the customer (DoD, DOE, Department of Commerce) or other relevant natural resource trustees, such as the U.S. Department of Interior (USDOI) or a State natural resource management agency. By early planning (which may involve negotiations and documentation of understanding with the agencies), the applicable agreements/scope of work and other issues can be adequately addressed. This process should work well for risk assessment and other technical evaluations/data category requirements in the HTRW project. When a State requires an ecological risk assessment approach or sets cleanup standards substantially different from those of the EPA, the data needs to satisfy/supplement or reduce uncertainties in the State's approaches should also be considered early in this project planning process.

time/budget, site and project strategy, preliminary work acquisition strategy, and definition of PDs for data users to identify data needs (Phase II of the technical project planning process). With this information, the HTRW site's PMP can be developed or modified.

D.2.2 Phase II - Identify Potential Data Needs to Support Decisions

Phase II of the technical project planning process focuses on identifying the data needs and minimum data quality requirements to support site decisions identified in the PDs. Phase II activities to identify data needs include:

- Review of the preliminary ECSM and identification of project study elements (key deliverables or work output) to satisfy PDs for the current executable project phase. For the risk assessor, the following project study elements may be appropriate:

  - Determine if the site should be eliminated based on the lack of ecological concern, specifically, the lack of valued resources to be protected and/or the lack of food sources to support sensitive ecological species.

  - Assess baseline ecological risks to determine the need for remediation.

  - Identify or develop potential risk-based PRGs, wildlife concern levels, or benchmark values.

  - Evaluate the appropriateness of early actions, interim measures, presumptive remedies, or accelerated cleanup/removal actions, especially for hot spot areas, to eliminate or mitigate current exposure to ecological receptors.

  - Evaluate potential early actions or remedies for their potential ecological impacts during response actions or after the remedies have been implemented, including the estimated time for recovery.

  - Support RD/RA criteria (e.g., source control via construction of a slurry wall and diversion of runoff away from a nearby stream containing valued game fish species).

- Conceptualize data needs to support the relevant project study elements. For the risk assessor, the data needs should be used to:

  - Refine the ECSM, if applicable (i.e., identify additional potential ecological receptors or potential exposure pathways; assess pathway completeness and the significance of actual or potentially complete pathways, including potential biomagnification across trophic levels), multiple ECSMs may be needed to address common sources or locations, transport/migration pathways, and target receptors.

  - Identity applicable inference or linkage between measurement and assessment endpoints and/or other sets of endpoints and the strength of such correlations.

- D&ermine data needs by focusing on data need categories and the ECSM critically evaluating their uses or application (based on project background information, requirements of PDs, and project study elements) to this or subsequent project phases.

  [Chapter 4 of the HTRW Technical Project Planning Guidance provides general site investigation data needs checklists and an example ECSM to illustrate the process for data needs determination. A checklist for ERAS, entitled *Super-fund Program Checklist for Ecological Assessment/Sampling* (EPA 1993a), provides basic information and data needs for a qualitative screening evaluation of a COEC at a site. The risk assessor may also consult with a specific EPA Region or State for similar checklists.]

- Document data needs by identifying the data user (risk assessor), the intended use, and data quality appropriate for the use? For the risk assessor, the data needs should be documented by:

[3] As discussed in Section D.4, the risk management decisions associated with the PDs will be supported by the data collected for the ecological risk assessment or analysis. The required quality should be appropriate to the level of acceptable data uncertainties in the risk management decisions. See Chapter 9 for details regarding risk management decision-making and evaluation of uncertainties.

- Segregating data types and grouping them by pathway and ecosystem, i.e., source area, medium, sampling location ***or*** depth, target receptors, etc., based on established site information and the ECSM.[4]

- Specifying an acceptable confidence level in terms of data variability or ranges of data uncertainty, particularly in the testing of hypothesis[5]

- Preparing data needs worksheets for each pathway which document data types and locations, and associated QA/QC requirements (including the percent minimum detectable relative difference [MDRD] and acceptable confidence levels). Examples of data needs worksheets are presented in the HTRW Technical Project Planning Guidance.

D.2.3 Phase III - Identify Data Collection Options

Phase III of the technical project planning process incorporates data needs identified from Phase II, and project constraints or preferences in designing a data acquisition approach. Phase III generally includes the following activities:

- Review of Phases I and II information to ensure that the requested data (documented in the data needs worksheets) submitted by all users are consistent with data use and am needed to fill data gaps for site decision-making.

- Conceptualization of the overall approach to satisfy data requirements, including data for the testing of hypotheses. This activity also considers chemical and physical characteristics of the site contaminants, particularly those of ecological concern (e.g., chemicals with a high bioconcentration factor [BCF]); location of sources: biological receptors: exposure pathways: media or biota to be sampled, and sampling strategies.

- Development of approaches for sampling and analysis activities.[6] This activity identifies and

[4] Relevant site information may include records of prior investigations at or near the site, removal actions, histay of operations, and documentation of the current or future land use (exposure setting) at the site as determined by the local land use planning authority or an independent land use expert, etc. Information may be site-specific or general. Published reports concerning the site geology, hydrology, or ecology may include: the Soil Conservation' Service's (SCS) soil map: the flood insurance rate maps and flood hazard boundary maps from the Federal Emergency Management Agency (FEMA); the USFWS wetland maps: topographic maps from the U.S. Geological Survey (USGS): and commercially available digitized flora/fauna data for the Geographic Information System (GIS). Risk assessors should evaluate these data for their applicability and useability based on the DQQ approach.

[5] The observed variability (total error) in any statistical analysis of a sample population represents bias in sampling (systematic error) and variability among the individuals in the population and/or the measurement (ability of the measurement tool to consistently record the true result vs random error). The data users specify the limits of data uncertainty by informing the data implementor/ statistician of acceptable confidence levels to protect against false positive or Type I error (rejecting the null hypothesis and stating the site is contaminated, when the site is in fact not contaminated) and false negative or Type II error (accepting the null hypothesis that the site is not contaminated, when in fact the null hypothesis is false and the site is contaminated). Based on acceptable uncertainty for protecting the ecological receptors or ecosystems, economics, and other criteria, the data user also defines a region of indifference when errors of either type are considered acceptable. Generally speaking, the Type I error may be as low as 80%, and the Type II error 90%. for the RI or RFI project phase. Lower errors may be suggested for other HTRW project phases for consideration by the customer or the regulatory agencies.

[6] In designing the abiotic sampling approach, purposive (judgmental), conventional statistical, or geostatistical methods may be considered to estimate the number of samples needed and their locations. At this stage, planning for the collection of paired samples for chemical analyses and toxicity tests should be considered. Additionally, the field screening or laboratory methods, sampling/data gathering techniques (e.g., composite vs. grab samples), and appropriate QA/QC checks should be evaluated to ensure that they meet quality assurance objectives for each (executable) stage of the project. These QA/QC checks may also include performing a regression analysis and establishing a correlational coefficient between the field measured data and confirmational laboratory analytical data.

screens for data overlap, defines potential sampling strategies, and recommends the most appropriate sampling and analytical methods (field or laboratory methods and their detection limits) based on data needs of current and future executable phases. Determining overlaps of data needs and combining preliminary options, as appropriate, should optimize data collection efforts. The data implementors (statistician, chemist, geologist, biologist, and others) work with the data users to clarify data needs, and to conceptualize potential sampling approaches.

- Evaluation of cost, schedule, technical feasibility of the sampling/analytical methods, elimination or minimization of potential confounding factors (e.g., effects of natural selection, seasonal fluctuation, etc.), strength of cause-effect relationships, and other constraints or benefits associated with the sampling approaches to arrive at data collection options. The trade-offs among requisite data quality and quantity goals to meet the prescribed confidence levels or error rates, and the above factors arc discussed among the data users, data implementors, the expert ecologist(s)/ advisory panel, and PM or TM. The data implementors determine data quantity based on the required data quality and confidence proposed by the data user. These activities include:

  - Quantify data to be collected. If relevant preliminary site data are available, the number of samples or data quantity needed can be estimated based on professional judgment and/or the need to supplement or confirm existing data. Alternatively, a statistical approach can be used to identify the required number of samples based on the ability to meet the maximum acceptable error rate (level of confidence) at an assumed or demonstrated data variability (variance) and the minimum detectable relative difference (MDRD) for the relevant area of investigation, area of ecological concern, or exposure area.

  - Establish data quality requirements. (For chemical data, QA/QC requirements include detection limits, types and numbers of QA/QC samples [i.e., blanks, duplicates, and control samples], frequency of sampling/analysis, and documentation).[7] The objectives of these requirements are to provide a QA program (precision, accuracy, completeness, representativeness, and comparability) for the chemical data to be collected. For nonchemical types of data, e.g., establishing comparability among reference (background) locations or assessing aquifer properties used in contaminant transport modeling, a separate set of

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[7] Duplicates are usually two samples collected at the same time and location as a measure of homogeneity of the medium and the precision in sampling. Replicates or splits usually originate from one sample that is divided and sent in the same sample delivery cooler/package to the same laboratory as a check of laboratory instrument precision and accuracy (replicate samples may be split for independent analysis by different laboratories for comparability of analytical results). Field blanks are samples of contaminant-tree medium that are either transferred from one sample container to another in the field or exposed to field conditions (at the same duration of sampling and sample preparation) for use as an indication of sample contamination during the entire process of field sampling and sample processing. Trip blanks are needed for samples collected for volatile organic compound (WC) analysis; they are samples of contaminant-free media, which are kept unopened, and which accompany the site VOC samples as a measure of cross-contamination during collection, shipment, and storage. Rinsate blanks are samples of deionized water that are run over the sampling equipment, after decontamination of the equipment for use as a measure of adequacy of decontamination procedures and potential cross-contamination. Laboratory control samples are samples of the control matrix spiked with certified reference materials or analytes that are representative of the target analytes. These samples are used to verify the precision and bias of the analytical process, i.e., the results are compared with control limits established for the analytical method to determine data useability. Other laboratory control procedure samples are the matrix spike and the matrix spike duplicate which are used to document the effect of matrix interference on the analytical method performance, and method blanks, which are used to assess laboratory-induced contamination.

quality assurance requirements will be established and can be done on a case-by-case basis.[8]

- Document data collection options by identifying sample types (media), numbers, locations of the sampling stations, and sampling and analytical methods. A sampling plan may be prepared at this time to communicate data collection options and to provide a rough cost estimate (order of magnitude) for each recommended option. It is preferable that three options be developed for selection by the customer and other site decision-makers. The project team should also recommend the optimum collection program for consideration by the decision-makers.

The key output for Phase III is an array of data collection options which can be presented to the customer and decision-makers for option selection under Phase IV. The data collection options presented must be consistent with the customer's goals and concept of site closeout, time/ budget, site and project strategy (especially, logical arguments and steps to be taken in linking the field measurements to the assessment endpoints), PDs, and the project study element(s). The Phase III technical project planning process output which is an array of data collection options should be able to:

- Incorporate data needs of the data users and define the "right" data types for development of DQOs (for the current executable phase, subsequent phases, and/or the project as a whole).

- Reduce areas of data collection overlap (e.g., those requited for preliminary remedial design, human health risk assessment, ERA, and preassessment screen of potential NRDA actions [if applicable]).

- Meet budgetary, schedule, and administrative (FFA, IAG, regulatory compliance) constraints.

- Meet QA/QC requirements and predefined acceptable uncertainty criteria.

Since the data needs are driven by site decision requirements, e.g., those related to the ERA, the ECSM provides the cornerstone for the data collection table development. Table D-l outlines the linkage between the ECSM and data collection strategy for conducting a baseline ERA.

D.2.4 Phase IV - Select Data Collection Options and Assign DQOs

The Phase IV technical project planning process involves the selection and documentation of the data collection program in support of an ERA or risk analysis. Such documentation will provide a historical knowledge which justifies and guides the data review and data use. Phase IV includes the following activities:

- Preparation of a fact sheet or matrix table summarizing the data collection program options. The fact sheet assigns costs and presents characteristics of each data collection option (e.g., types of sampling and analysis activities, numbers of samples, benefits, uncertainties or limitations, schedules, technical requirements, and other constraints). To support the PM or TM in preparing the fact sheet or the matrix table, the risk assessor identifies the project study element and data needs required to complete the study element. The risk assessor should document which arc the critical samples or field survey activities and those data or parameters which are sensitive and, therefore, require a higher level of QA/QC. In addition, the risk assessor provides rationale for tradeoffs in quality, quantity, and sampling methods, the anticipated benefits: and data uncertainties for the fact sheet/matrix table.

- Design of a data collection program. This activity includes presenting the data collection program options to the customer/decision-maker, refinement of the customer/decision-makers' preferred option; and final selection of an option.

[8] For example, the customer determines that fate and transport information is needed to demonstrate a low environmental concern to the aquatic receptors from the potential migration of groundwater to surface water. After the data implementor has consulted with the hydrogeologist/modeler (data user) assigned to the HTRW project, this data implementor may recommend to the TM and the project team that a simple one-dimensional model, although more conservative, may be a better choice than a three-dimensional model, given the time and budget constraints for a particular project phase.

Table D-1
Linkage Between ECSM and Data Collection Strategy

ECSM (Null Hypothesis)	Linkage (Accepted/Rejected)	Data Needs (Qualitative/Quantitative)
The ECSM indicates a potential for exposure of a valued ecological receptor population via Pathway X; within a defined confidence interval, the risk is acceptable	Current vs. Future scenario: plausible/ not plausible	In support of the null hypothesis, qualitative data and/or quantitative data will be presented in the risk assessment
Receptor types	Likelihood receptor types present: High/Low	Land Use/Field Reconnaissance or Survey to identify indigenous or surrogate species that are sensitive to the COECs and are biologically relevant to the assessment endpoints or resources to be protected
COECs	Site related vs. reference or non-site-related sources	History or records of operations/sampling of media to demonstrate comparability of site characteristics at reference locations
Potential for release/transport	Physical and chemical properties of COEC and source matrices, and the physical/chemical characteristics of the transport medium: amenable/not amenable	Literature values, structure-activity relationship (e.g.EPA's QSAR), bioavailability (acid volatile sulfide/simultaneously extracted metal [SEM/AVS] ratio), binding characteristics (organic carbon contents), measurement data of medium flow or speed and COEC transport characteristics
Exposure point concentration estimate	Considerations for chemical fate and attenuation; uptake and excretion: reasonable/unreasonable	Professional judgment based on physical, chemical and biological properties of COEC in media, boundaries or barrier/ measurement or predicted (modeled) values
Toxicity assessment	Exposure-response relationship including assessment methodology is appropriate/not appropriate	Preponderance or the weight-of-evidence assessment of uncertainties (a discussion of the strength and limitation of the data) for this tier and phase of data collection strategy

- After the data collection program option has been selected by the decision-makers, the project team documents the selected option by finalizing DQOs and scope of work sections and prepares a detailed cost estimate in support of the decision document.

It should be emphasized that in the process of deliberations of data collection and design options, the customer may decide to eliminate, reduce, or modify the quantity of data collected if the customer feels that they are not critical to supporting DQOs and decision-making. For example, if the customer is very familiar with the site history and has the operating records/supporting data, he or she may decide that only compounds X, Y, and Z arc the only COECs. The sampling effort should therefore focus on these parameters for subsequent chemical analysis, and not the full Target Compound List (organics), Target Analyte List (TAL), 40 CFR 261 Appendix VIII or Appendix IX chemicals. If tissue samples arc analyzed for chemical residues, those chemicals with little or no potential for bioaccumulation (e.g., volatile organic compounds) should not be included in the list of analytes. A good understanding of the ECSM, the chemical properties and fate, and the regulatory decision-making process in the HTRW program is a key factor which will affect a productive team effort in this final technical project planning phase.

D.3 Rob and Responsibilities of a Risk Assessor In the Data Quality Design Process

The purpose of the HTRW data quality design process is to implement Total Client Satisfaction (TCS) and Total Quality Leadership (TQL) programs. To do so successfully, each project team member, under the leadership of the PM or TM, participates and works cooperatively with other team members to develop data collection program options for the customer. Such options cannot be truly developed without a thorough understanding of several key elements. This section addresses these key elements and defines the role and responsibilities of the risk assessor regarding site strategy development, identifying PDs, and defining study elements and data needs/quality to support risk management decisions. With a clearly defined role and responsibilities, the risk assessor can be more focused in serving the customer so that quality data collection options can be developed.

D.3.1 Site and Project Strategy Development

Under Phase I of the HTRW technical project planning process, the technical planning team members work with the customer to develop the overall site strategy for the current and subsequent executable phases of the project. Further, the site future uses, probable remedies, and options to achieve site closeout are identified in this phase. Therefore, a thorough review of the site history and background information by the risk assessor will help fulfill his or her role/responsibility in assisting the strategy development. It is also imperative that the risk assessor understands the customer's goal, concept of site closeout, and communicates his/her thoughts and suggestions to other team members with respect to the following areas:

- The risk assessment requirements for the primary and secondary regulatory programs. These requirements may range from a qualitative determination of whether or not there is a valid ecological concern, a screening ecological assessment, a baseline ERA, development of PRGs to protect valued ecological resources, and risk (ecological effects) screening of potential remedial alternatives. It should be noted that some risk assessment requirements may be simple and others complex with respect to data needs. The risk assessor should be open and candid about such risk assessment or risk analysis requirements, potential assessment approaches and their associated costs and time requirements, and their strength and weaknesses as inputs in making site decisions.

- Implications of current and future land use and risks. The risk assessor should explain to the project team members and the customer how current and reasonably anticipated future land uses (according to customer's goal) are factored into assessment of available food sources, habitats, and exposure to site contaminants for sensitive ecological receptors. Furthermore, any direct and indirect effects to be measured should also be explained.

- Expert advice or inputs. The risk assessor may present arguments and rationale to the expert ecologist(s)/advisory panel regarding whether the assessment endpoints (species or the resources to be protected) are appropriate, or the rationale for the lack of significant ecological concerns.

- Site background information review and development of preliminary ECSM(s). The risk assessor should review all site background information, especially the general site geology/ hydrology: potential COECs or the nonchemical stressors; the physical and chemical properties of the stressors; and their release, migration, transport, and fate properties. The objective is to conceptualize and refine the preliminary ECSMs for use in evaluating potential site closeout options and guiding selection of data needs in Phase II of the technical project planning process.

- Short-term and long-term reliability of potential remedies, technologies, or removal actions. Under Phase I, the probable remedies and site closeout options am identified. The types of remedy or technologies employed should be thoroughly evaluated by the risk assessor. The evaluation should focus on the ability and reliability of each alternative to reduce ecotoxicity, exposure, and risk, as well as their impact on existing habitats and potential recovery of such habitats after implementation of the proposed actions or removal of the nonchemical stressor. These technical comments should be based on the ECSMs.

- A "sanity check" or a check of implementability and data useability for potential study elements. It is the responsibility of the risk assessor to identify constraints, benefits, and shortcomings of employing certain assessment techniques or data gathering activities. The objective is to

keep the project team in focus so that ancillary and research projects without benefit or gain in knowledge for the customer's site decision-making are not pursued. Essentially, the risk assessor looks out for the customer's interest and critically assesses if a particular study or data requisition is warranted.

To summarize, the risk assessor plays the role of a key project team member (other key members are responsibility-legal; remedy-design engineer: and compliance specialist) and interacts with the customer, PM, TM, and other team members to develop the overall site strategy and strategy for the executable project phases. The risk assessor contributes to development of the strategies through communications and dialogues of his or her knowledge in ERA requirements for the pertinent regulatory programs, implications of land use or risk, and viability of certain site closeout options and remedies based on the preliminary ECSMs. Where appropriate, the risk assessor consults with the expert ecologist(s) or the advisory panel and forges a consensus based on PDs regarding problem identification and formulation, the assessment approach, data adequacy, cause-effect relationships between stressors, and any observed environmental effects.

D.3.2 PDs and Study Elements

Under Phase II of the HTRW data quality design process, the technical planning team members conceptualize potential data needs based on understanding of the site and project strategies and decisions to be made under the applicable regulatory program. In doing so, it is the responsibility of the risk assessor to understand and articulate the basis for the PDs in terms of the risk assessment inputs in making the site decision. The risk assessor identifies the project study element for the current phase and subsequent phases (if appropriate), and conceptualizes/defines data needs in support of the project study element.

It is also important that the risk assessor and the PM/TM have a common understanding of the project study elements and the objectives/utility of the elements to support site decisions. Where the study element will be a cooperative effort among project team members, the elements have to be communicated and understood by all affected members. For example, a field survey to establish the existence of sensitive environments and valued resources or the collection of co-located media samples for toxicity testing to establish RA objectives can be integrated into the field investigation activities to identify the locations of "hot spots" under an engineering evaluation/cost analysis (FE/CA) for a potential removal action. In another example, quarterly groundwater sampling of monitoring wells could be integrated into the same study element to monitor the community structure or health (diversity and abundance) of indicator species such as benthic macroinvertebrates at the reference locations and downstream locations of a site for a long-term field survey. The risk assessor should communicate his or her thoughts and suggestions with respect to the following areas:

- Study elements to be performed and breakout of the elements. The data needs for the element and its subelements have to be conceptualized and identified. The risk assessor and other team members need to identify the study element or subelement which may be executed by other project team members.

- Provide rationale for data needs in terms of useability in satisfying information requirements for PDs. The risk assessor presents to the PM/TM or the affected project team members' thoughts/ideas and data requirements for executing the study element. The risk assessor may find these communications helpful because other project team members may be able to identify data sources or provide alternative approaches to satisfy data needs.

- Define and document data needs. With an understanding of the PDs and rationale for making site decisions, the risk assessor has the responsibility to define data needs and explain how the data will be used in the study element in support of site decisions. The risk assessor has the responsibility to articulate data needs based on the ECSM, and recommend data quality and confidence levels (applicable for abiotic or certain biotic sampling) for a particular information need on the data needs worksheet.

- Sensitive data or critical samples. Where the information or parameter is sensitive as to its effect on the result to the study element, the risk assessor should identify these parameters to the project team. The strength and weakness of the requested data in making inferences, testing of a hypothesis, and providing the weight-of-evidence presentation with respect to analyzing uncertainty in the ERA should also be discussed.

To summarize, the risk assessor plays the role of a key project team member and interacts with the customer, PM, TM, and other team members (as appropriate) to conceptualize data needs. The risk assessor has the responsibility to justify the data needs based on the ECSM and the requirements of the project study element. The data needs are defined and documented formally, e.g., using data needs worksheets.

D.3.3 Data Need/Quality to Support Risk Management Decisions

Under Phase III and Phase IV of the HTRW technical project planning process, the risk assessor and other project team members identify sampling approaches and data collection options, refine options, and document the selected option. Negotiations and tradeoffs are anticipated during these project planning phases because data needs, quality, and confidence levels may not be completely satisfied due to budget, schedule, and other constraints. The risk assessor's responsibility is to identify and communicate to the data implementors key data needs and their associated desired quality and confidence level needed for the project study element. Among others, it is the responsibility of the risk assessor to stay focused, only requiring those data pertinent to support risk management decisions. The risk assessor should communicate his thoughts and suggestions with respect to the 'following areas:

- Sampling approaches and analytical requirements. Based on site background information and the preliminary ECSM, the risk assessor should have already provided input to the data implementors and TM on the types (medium-specific), desired confidence level, time and location for the samples under Phase II. These requirements should be based on the ECSM and the physical/chemical characteristics of the COECs (if known) and the site matrices. If certain COECs are suspected, the risk assessor should review their respective PRGs or benchmark levels, and ensure that the analytical limits are below such levels. This approach applies to both biotic (e.g., tissue residue analysis) and abiotic samples. In Phase III, the risk assessor communicates and explains data needs and quality assurance requests to the data implementors.

- Refinement of data collection options. Based on consideration of project constraints, and customer's preference/input, the proposed data collection program options may require refinement. This may involve phasing the site investigation or addressing certain "hot spot" areas first or limiting the study ares to the EU or area where the sensitive receptors or valuable resources may be at risk. The risk assessor can contribute substantially to this refinement effort by identifying the major exposure pathways and media of concern.

- Field survey/site reconnaissance. The risk assessor should conduct a thorough site reconnaissance and review all site references and background information before developing the ECSM for use in identifying complete exposure pathways and the exposure point (medium). This site visit and review also serve to verify the feasibility/practicality of exercising certain field data collection options, including locations of the sampling stations and the existence of biota to be sampled. Data collection options should be presented to the decision-makers in a clear and concise manner, e.g., matrix tables supplemented by bulletized discussion of the advantages and disadvantages, including data uncertainty associated with each option.

- Optimization of the data collection program. The risk assessor works with other project team members to prioritize data needs, if necessary, and identify the optimum sampling strategy or cost-effectiveness ideas. As a key member of the project team, the risk assessor should review past site data and anticipate data needs for future project phases to incorporate cost-effective data strategy into the data collection option(s). (In addition to chemical data, incident reports, environmental impact studies, or fish or wildlife consumption advisories published by local college/university, natural resources department, State fish or wildlife conservation districts should be reviewed) All data collection options must be able to satisfy the short-term and long-term goals.

- Assignment of DQOs. Statements concerning data needs and use and their benefits/limitations in support of project decisions should be prepared for presentation to the customer in the form of a fact sheet for a particular option. After the data collection program option is selected, the risk assessment finalizes such statements as DQOs for use in the TM package or the scope of work for work acquisition. An

essential element in a particular DQO is the decision statement (if-then) regarding data outcome and options. The DQOs should comply with the customer's request for information to make informed site decisions. For example, if the assessment endpoint is protection of downstream bivalves or oyster beds during sediment remediation and the measurement endpoint is a combination of COEC concentration in the boundary sediment and turbidity (expressed as total suspended solids), the DQO statement may indicate the maximum frequency of exceedance of these parameters during a specified time period, say 12 hours. If exceedance occurs, then sediment dredging is suspended until normal conditions are reestablished.

Playing the role of a key project team member, the risk assessor supports development of viable data collection program options by identifying key data needs and their required level of confidence and quality. The risk assessor has the responsibility to identify the benefits and limitations of certain data and develop the appropriate DQOs for obtaining such data. The risk assessor also has a responsibility to work with other project team members to optimize the data collection program options consistent with the overall site strategy and the customer's goals.

D.4 Data Needs for HTRW Executable Project Phases

For scoping of data needs to perform a risk assessment or a risk analysis, the risk assessor and the PM/I'M agree on the project study element for that executable phase. The study is focused on providing the exposure and risk information to support risk management decision-making for the PDs.[9] Key PDs are statutory or regulatory requirements which have been identified for each HTRW executable project phase in the HTRW Technical Project Planning Guidance. To assist the risk assessor and those who oversee performance of the risk assessment/risk analysis (e.g., PM, TM, and the customer), this section provides a framework for identifying data needs associated with typical study elements for HTRW executable project phases under CRRCLA and RCRA (i.e., PA/SI and RFA; RI and RFI; FS and CMS; RD/RA and CMI). Typical data needs are also presented for these project phases. It should be noted that data needs should not be

[9] For the purpose of this manual, the project planning approach used to identify data needs pertains to assessing ecological risks posed by the site under the baseline or no-further-action scenario. If removal or remedial actions are warranted, data will be needed to derive remedial action objectives (cleanup goals) and to perform screening or detailed risk-based evaluation of the short-term and long-term impacts from the potential removal or remedial alternatives. In addition, the risk assessors may be requested to coordinate with other technical planning team members to provide inputs and help define data needs for other site evaluations. These requests may be for the planning of certain response actions, e.g., compliance/cleanup verification levels based on uncertainty of the risk-based remediation action objective; assignment of response action responsibility based on the contribution to site risk from multiple releases into the environmental medium, etc. These data scoping activities are not the focus of this section, although the general approach for scoping the data needs may be applicable.

finalized until a review of the existing data has been conducted to determine data gaps.

The framework for conceptualizing and defining risk assessment data needs consists of the following steps, which are in accordance with the HTRW Technical Project Planning Guidance:

- Background information review (Step 1) -- The purpose of this review is allow the risk assessor to become familiar with site features, hazards (potential COECs or nonchemical stressor[sl to be evaluated), available exposure-response or toxicity information, and exposure (potential exposure pathways). The review assists the formulation of the problem, evaluation of potential ecological concerns, and the development of the preliminary ECSM.

- Assemble PDs and identify project study elements specific for each PD (Step 2) - The purpose of this step is to identify the decisions to be made so that the study element or the type of ERA or risk evaluation can be established to support decisions.

- Conceptualize data needs based on the ECSM (Step 3) - This data scoping step requires the risk assessor to identify data needs based on the ECSM and the study element required. Existing chemical, nonchemical, or exposure data can be used to characterize exposure to ecological receptors (both spatially and temporally) with or without the application of fate/transport or other models (e.g., food web models).

  [As appropriate, the risk assessor may also consider data needs in future project phases in order to refine the ECSM or to facilitate risk evaluation of anticipated removal or remedial actions (if such needs can be more cost-effectively satisfied by the data collection program in the current project phase)].

- Define and group data needs (Step 4) -- This scoping activity entails defining the necessary data (i.e., data gaps) based on earlier steps, and groups data needs by medium, location (spatial attribute), or time (temporal attribute). For example, quarterly sampling of groundwater intersecting the surface water (seep samples) to estimate the exposure point concentration of COECs for freshwater species to be protected.

- Document data needs (Step 5) - This step requires the risk assessor to document the data needs by providing the basis or reason for the data, how the data are to be used to help make site decisions, and the proposed data quality and confidence level. The documentation is needed so that a record is established to identify the originator of the data request, the application or use of the data, and the required quality. Since environmental data could be reported in any manner to tit the user's need, the risk assessor may also document and communicate such data compilation needs in this scoping step.

The following sections present the scoping requirements for a risk assessment or risk analysis performed for the HTRW project phases. For each project phase, the section identifies the type of background information usually available, the PDs for the project phase, typical project study element(s) to be performed, and the data needs/ groupings. The discussion of data needs focuses on why such data are needed and how they are to be used. The discussions are not intended to be all-encompassing: data needs depend very much on the project study element, amount of useable data already in existence, and site-specific conditions.

D.4.1 Exposure Pathway Analysis and Risk Screening; PA/SI and RFA

Focusing on risk assessment/analysis data needs, this section discusses the HTRW data scoping for the preliminary site evaluation phase in CERCLA and RCRA. This site evaluation phase is known: under RCRA as a RFA; under the CERCLA removal (emergency response) authority as a Removal Assessment; and as a PA/SI under the CERCLA remedial program. Other HTRW site assessments, although not specifically covered under these statutes, e.g., the Baseline Environmental Survey in a BRAC, are expected to be functionally equivalent. The project execution phase for the PA/SI and the RFA is generally known as a Phase I project execution stage. For a Phase I project execution stage (i.e., PA/SI or RFA), the following technical project planning approach should be considered.

D.4.1.1 Background Information Review

Before the data needs are conceptualized, it is recommended that the risk assessor (and the technical planning team members) carefully review all site background information including: TM Memorandum: RCRA Section

3019 exposure information for land disposal and certain land treatment units (if applicable): file searches (available State and/or EPA enforcement or incident reports, fish and wildlife consumption advisories, Prescore of the HRS, SI Worksheets, HRS scoring package, checklists, notes and photos documenting the site's environmental setting, etc.): USGS or State geological survey bulletins/ references and topographical and National Wetland Inventory Maps; State Fish and Wildlife Department information on fisheries, endangered or threatened species/ habitats; EPA databases (Geographic Exposure Modeling Systems [GEMS], PATHSCAN [surface water information], etc.); aerial photos; and the commercially available GIS digitized data package.

In addition, the data quality used to produce the SI or Expanded SI reports for proposed placement on the NPL (if applicable) should be reviewed, along with a determination of whether additional data are needed to support PDs. The purpose of this review is to obtain a good understanding of the following issues:

- Regulatory concerns or site problems relating to ecological receptors,[10] and the significant exposure pathways (source, migration/transport mechanism, exposure routes, and receptors) to be addressed.

- Status of the project with respect to an identifiable decision path leading to site closeout.

- Customer's or PM's goals and objectives, plan of actions, compliance requirements, and budget/ time constraints for the current phase and subsequent phases of the project life cycle (if known).

0.4.1.2 PDs

The following describes the decision step within the critical path of the HTRW response program relating to the CERCLA and RCRA SA phase:

- PA/SI -- Upon completion of a PA/SI, the critical path is likely to be elimination of the site from further action or, if the site score is above 28.5 on the I-IRS, for listing on the NPL, or require further investigations (under a RI/FS). The no-further-action decision may also include referral by the USEPA to the State for further assessment.

- RFA -- Upon completion of a RFA, the critical path is similar to that for the PA/SI, i.e., determine whether potential SWMUs can be eliminated from further action or should be further investigated in the RFI phase.

The above broadly defined decision steps in the project life cycle indicate that the type of decision to be made for the SA phase under these regulatory programs is similar to one another (i.e., "Should the site be eliminated from further investigation?"). The objectives for an SA at this early project phase concern the identification of past or current releases, locations, boundaries, assessment of the need for removal or interim measures, and documentation of all risk reduction actions. Logically, if there is no documented history of chemical releases or there are containment devices with good structural integrity to intercept the releases, there should be little basis for further action. On the other hand, if there were documented releases, the decision will have to be based on a more complicated analysis to ascertain: (I) the environmental significance of the release (based on limited medium contamination and an exposure pathway analysis); (2) the need for removal actions or interim measures to mitigate risks: and (3) priority of site actions (i.e., hazard ranking of this site relative to other sites) under the HRS or other prioritization schemes, such as EPA's National Corrective Action Prioritization System (NCAPS), guidance on setting priorities for NPL candidate sites (EPA 1992p), or the DoD's site ranking/prioritization system."

[10] In addition to the regulatory actions or concerns, the risk assessor should also review any draft or final reports from universities and the local or State natural resource agencies concerning the site environmental setting and ecological concerns. The regional USFWS should be consulted for the existence of endangered or threatened species, including Category 2 and rare species. The Army's BTAG may be consulted regarding the significance of any expressed ecological concerns.

[11] High priority is assigned by EPA to sites for which SIs have been completed and where (1) people are currently exposed to hazardous substances, pollutants, or contaminants: (2) actual contaminant has been documented, especially at or above a health-based benchmark: (3) a large potentially affected target population is nearby: (4) contamination to a sensitive environment or fishery has been documented: (5) the State has recommended the site be listed on the NPL pursuant to CERCLA 105(a)(8)(B); or (6) the ATSDR has issued a health advisory or is planning to.

On a project management level (not programmatic management level), items (1) and (2) above are the only relevant considerations. Therefore, specific PDs associated with this executable project phase are:

- Determine if the "site," SWMU, AOC, etc., can be eliminated from further action (i.e., investigation and/or remediation).

- Determine if removal action(s)/interim measure(s) are needed to mitigate imminent threat to human health or to the environment.

D.4.1.3 Project Study Elements

The objectives of the study elements (screening ERAs or risk screening) are to address the PD on whether or not the site should be eliminated and whether or not removal actions should be undertaken. Project study elements should provide evidence in support of or in refute of past or potential future release, transport, and human health/environmental impacts. Additional support can be provided by a hazard evaluation which considers the chemical identity, concentration, and/or volume of the past or possible future releases, or the nature, spatial and temporal attributes of the nonchemical stressor, and an exposure pathway analysis which includes the identification of ecological receptors of concern or valued resources.

For the SA project execution phase, preliminary quantitative chemical data are preferred, although not likely to exist, and qualitative information on the site setting (specifically, a habitat evaluation for the potential exposure to sensitive ecological species or valued resources) are needed for all or any one of the following project study elements:

- Perform a qualitative or semiqualitative screening risk evaluation by comparing limited site data (usually from purposive sampling of visually contaminated areas) to benchmark concern levels such as those identified in the USFWS contaminant review series by Eisler (1986-1988); NOAA's ER-L and ER-M values for sediments: Ontario's LELs and SELs; chemical-specific ARARs[12] such as State or Federal AWQC, Great Lakes National Program Office's sediment concentrations for PCBs, mercury, pesticides, and other chemicals: background concentrations: inorganic (mineral) nutrient levels, or other appropriate toxicity-based literature values (e.g., AQUIRE database).

- Conduct a qualitative exposure assessment, based on the ECSM, and identify completeness of potential exposure pathways and their significance or likelihood of release/transport which could result in exposure by the target receptors. The assessment should also consider: the size of the site containing the chemical contaminants in relation to the foraging range of the target species to determine the EU, the physical and chemical characteristics of the contaminants (including the bioconcentration and biomagnification potential): and media matrices.

- Conduct HRS scoring using PreScore/SI Worksheets to determine the contribution of the environmental concerns to a HRS score, and to determine if potential early actions/removal actions or update of information may significantly reduce the need for or the scope of a future CERCLA action.[13]

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[12] Other than Federal and State AWQC, which are a ready, frequently used source of chemical-specific, ecologically based (pseudo-risk-based) ARARs, essentially there are no chemical-specific ARARs for ecological concerns. Additionally, cleanup to an ARAR does not necessarily equate with attainment of protective levels.

[13] The results of this review and HRS scoring exercise should be presented to the Customer/PM. If the risk assessor can justify a lower HRS score or an insignificant risk, based on site-specific information, a request for regulatory relief (delisting, modification of permit conditions, etc.) to the agencies may be considered. This approach may also be useful to eliminate or prioritize SWMUs for a RFI.

- In limited cases where there are available chemical data, a screening risk assessment may be performed by employing mean and maximum observed concentrations, and conservative exposure assessment assumptions and models. This screening risk assessment may include the use of conservative BCFs, BAFs, fractions of soil and vegetation ingested by a herbivore; the equilibrium partitioning (EP) model to predict pore water concentration in wetland sediment (applicable for nonpolar organic compounds): or box models or limited dilution models to predict the exposure point concentration for a mixing zone between groundwater and surface water for aquatic organisms.

The above project study elements may discuss current and future land use and population characteristics, based on the discussion of potential exposure pathways. The study or evaluation may employ the weight-of-evidence approach to present potential risk qualitatively and indicate uncertainties of the evaluation. The exposure pathway analysis and recommendations should focus on the potentially complete pathways. The PA prescore may also be used to justify whether or not a RI/FS, RFI/CMS, or removal actions/interim measures are likely to be needed.

D.4.1.4 Conceptualizing and Defining Data Needs

Data needs for the risk assessment should be based on the preliminary ECSM(s) which should be established in this phase of the HTBW project planning process, and should generally be limited to responding to the above-defined PDs. The data needed may be nonchemical in nature, e.g., USGS 7½- minute maps, U.S. Chamber of Commerce Census reports, County Soil Maps, aerial photos, surveys, interviews with local conservationists/naturalists, or other sources of information that can be used to establish the existence of potential exposure pathways and receptors. The data needed may also be chemical in nature, e.g., sediment and surface water quality data of potentially impacted wetlands. In other words, the site strategy and PDs developed under Phase I of the HTBW project planning process will be the focus of this data-scoping activity. The output of this data-scoping (Phase II) activity are the Data Needs Worksheets for this SA (or Phase I) project execution phase or subsequent phases of project execution.

D.4.1.5 Establish Preliminary ECSM(s)

To establish the preliminary ECSM the risk assessor should focus on obtaining information needed to relate risk associated with the site and assess potential early/ immediate response actions. Ihe ECSM, described in greater detail in Chapter 3, presents all potential exposure pathways (sources, release mechanisms, transport media, exposure points, exposure routes, and receptors [including the relationships among receptor populations in a community and across trophic levels]) and identifies those pathways which are complete (significant or insignificant) and incomplete. The information should be able to assist the risk assessor in developing a preliminary ECSM or multiple ECSMs if there are multiple SWMUs, AOCs, OUs, or CAMUs/TUs or if there are multiple ecological receptors for these groups of sites or SWMUs. The CAMUs and TUs are most pertinent to the risk assessor for addressing remediation risk (Phase III project execution phase) from nonchemical entities since they encompass the boundary where remedial activities will be conducted. The risk assessor and project team members use the ECSM to focus the data collection effort on those significant pathways that may pose potential risks or food-chain effects and to address PD requirements.

Existing data should be reviewed for their quality and use in defining new data acquisition requirements for a preliminary or screening risk assessment/risk analysis and for a baseline risk assessment. Any uncertainty in the preliminary ECSM due to data gaps should also be identified in the ECSM. Information needed to develop an ECSM includes:

- COECs (information concerning the source characteristics, ecotoxicity, BCF, BAF, potential laboratory or field sample contamination, background and concentrations).

- Potential target media (groundwater, surface water, soil/sediment, and air).

- Potential receptors (endangered, threatened, sensitive, and rare species) and their home ranges, and resources of commercial or recreational value to be protected in the target media.

- Major exposure routes or pathways of concern (e.g., ingestion of chemically contaminated fish by raptors).
- Known release or likelihood of a release of a site chemical from a source, and the manner in which the release could occur.
- Level of contamination when compared to available ARARs, benchmark values, or PRGs.
- Data useability factors, based on quality assurance characteristics, parameters analyzed, validation results, and the way the data were compiled, that may severely restrict their use in the risk assessment (e.g., total organic halogen and soil gas data, combination of deep soil and surface soil data sets, low recovery of internal standards, etc.).
- Removal actions or interim corrective measures taken since site listing or report publication, which may have substantially mitigated exposure and risk.
- Areas or units which have COECs and exposure pathways in common and which pose a common threat to human health and the environment.
- Potential secondary sources of contaminants, and their release/transport mechanisms.

D.4.1.6 Define Data Types and Preferred Data Quality Requirements

Generally, the data needs for a Phase I project execution phase (or SA phase) are qualitative in nature and do not require intrusive field investigations, although field surveys (e.g., habitat evaluations) could be highly beneficial to identify the basis for ecological concerns. Where chemical data are desirable to confirm the presence or absence of releases, a Phase II HTRW technical project planning activity should be employed to define the data type according to complete or potentially complete exposure pathways. The pathways may include soil and groundwater ingestion, ingestion of food chain products, and direct contact or co-occurrence of the receptors with the contaminated media in space and time. The corresponding chemical data to assess such exposure pathways include soil, groundwater, food chain products, and airborne contaminant concentrations. The ECSM should be used to organize the corresponding relationships. As a data user, the risk assessor defines the exposure AOC for a pathway, the data quality needed, and preferred sampling strategy or methods. Examples of data types, according to medium, for use in assessing potential exposure pathways are:

- Surface soil (ingestion/dermal contact and inhalation of airborne particles).
- Surface water (ingestion/dermal contact).
- Groundwater (generally limited to the mixing zone only).
- Contaminated food (ingestion - the food web investigated can be simple involving one trophic level, or complex, involving different trophic levels).

The risk assessor then prepares Data Needs Worksheets for each pathway which document the data types, quality requirements, or needs. For example, the QA/QC requirements could be set as medium or low (QA3 or QA2).[14]

[14] EPA has identified three or more levels of QA/QC objectives based on the intended data use (EPA 1992d,e): (a) QA1 is a screening objective to afford a quick, nonrigorous. and least expensive (time/money) preliminary assessment of site contamination. It produces data for which there are neither definitive identification of the chemicals nor definitive quantitation of their concentration levels, although a calibration or performance check of method is required along with verification of the detection level. Applicable activities are: sample's physical/chemical properties, extent of contamination relative to concentration differences, delineation of plume in groundwater (head space or soil gas analyses), placement of monitoring well, waste compatibility, preliminary health and safety check, nonanalyte specific categorization, and preliminary identification/quantitation of chemicals (e.g., pH, ignitability, chlorine presence, etc.); (b) QA2 is a verification objective which requires a minimum of 10% verification of chemical identity (by an analyte-specific method) of the field or laboratory results, and a minimum of 10% verification of quantitation (accuracy of measured concentrations). It is intended to give the data users a level of confidence for a selected portion of preliminary data. Applicable activities are: sample's physical and chemical properties, extent and degree of contamination, and verification of plume in groundwater, health and safety check, chemical identification, and cleanup. (c) QA3 is similar to QA2 except that 100% of sample results are confirmed for identity, e.g., the use of GC/MS analytical method. That level is most appropriate for critical samples used to support site decisions. Applicable activities: comparison with action levels, treatment/disposal, site removal/remediation, health risk assessment, source identification/delineation, and cleanup verification.

The level of confidence (maximum error rate) required of the sample results should not be set so high, or the detection limits so low, as to be unrealistic and unachievable, considering the potential variability of the sample results in a given matrix and the available analytical techniques. However, it should be noted that chemicals which bioaccumulate cannot be effectively eliminated based on low concentrations or concentrations below nondetection. In this instance, analysis of tissue residues may be appropriate in future project phase(s), i.e., in the RI/FS or RFI/CMS project phase. For nonchemical types of data, the quality assurance requirements are established and done on a case-by-case basis. The risk assessor may utilize a weight-of-evidence approach to assess the data needs and their uncertainties in the SA project phase. The approach generally consists of qualitative data, such as from a site reconnaissance, to identify if there is stressed vegetation or dominance of tolerant species commonly found in contaminated sites. Subsequent collection and analyses of abiotic (media) may be performed in some cases to aid making informed site decisions at this stage of the HTRW response process. For example, soil discoloration and vegetation stress at the downgradient location (of a hazardous waste storage area) were observed where runoff is likely to take place. A small number of selective surface soil samples will be sufficient to make the decision on whether release from the source has occurred and to ascertain if the release is still localized.

D.4.1.7 An Outline or Summary of the Approaches In the Risk Assessment/Risk Evaluation, Uncertainty Discussion and Recommendations

The approaches or contents of an anticipated risk assessment/risk evaluation summary should be explained or made known to the decision-makers in the project planning stage in unambiguous terms. This is to avoid potential misuse of the risk assessment results, and can be used as a means to make sure that the selected data collection option will meet the users needs.

Due to limitations in data quality and quantity, the risk assessment/risk evaluation performed in a PA/SI, RFA, or in other site assessments is generally qualitative in nature, e.g., a discussion on the potential exposure pathways and preliminary ECSM. In the rare instance when a quantitative risk assessment is performed (e.g., the Toxicity Quotient Method), the results should be considered preliminary and screening in nature since the nature and extent of the contamination is not clearly defined at this time. In both cases, the uncertainty is considered high and should be identified as such by the risk assessor in a qualitative discussion. A quantitative assessment of uncertainty, using Monte Carlo analysis or other quantitative methods to propagate error, is not appropriate because this type of risk assessment or analysis is not meant to be used as a predictive tool. The recommendations derived from the assessment are general, i.e., the recommendations are expressed as “likelihood,” “probable,” and “deterministic.”

The preferred level of confidence for nonchemical data could be ranked medium to low. These levels of confidence are justifiable within an SA stage when different data inferring the presence or lack of environmental risk are collected, and a weight-of-evidence discussion of uncertainty is used to explain the evaluation findings and the recommendation(s). For example, the topography, visual observations, history of spills, runoff pattern, and the analytical results of purposive sampling would be sufficient, as a whole, to support the argument whether contamination of a medium is likely or unlikely.

If chemical data are available, the level of confidence will depend on the experience and expertise of the laboratory to deliver quality data, associated QA/QC control, sampling method, sample handling/preservation method, and last, but not least, variability of the chemical concentrations in the medium that was sampled. It is recommended that the risk assessor and chemist/data reviewer coordinate their efforts to design a sample collection program which is most likely to produce sample results with an acceptable level of confidence. The following factors should be considered in this planning activity in order to reduce uncertainties:

- Use of EPA-approved methods or ASTM protocols and the associated QA/QC for conducting chemical analyses.

- Laboratory QA/QC Program - A reputable laboratory with established internal and external audit procedures should be used. For analyses performed on a given instrument using a given analytical method, the laboratory should be able to provide a reasonable estimate of the range of possible values, given a detectable or estimated value in the data summary report. The laboratory should also conduct a preliminary QA/QC check before the laboratory results are finalized.

- Level of Quality Assurance - Depending on data use, the level of quality assurance for a PA/SI and RFA can be QA1 (field screening to assist

identifying sampling locations), QA2 (presence or absence of contaminants with some confirmational analyses), or QA3 (confirmational analyses of chemical identification and quantification, e.g., gas chromatography/mass spectrometry [GC/MSl method).

- Field and Laboratory QA/QC Samples - If soil or sediment samples are collected and are to be used in a future phase(s) of work, considerations should be given to collecting sufficient volumes for laboratory QA/QC analytical samples (i.e., duplicate, matrix spike, and matrix spike duplicate samples) and for field duplicates; water samples require field duplicates. In addition, samples for the analyses of 'volatile and semivolatile organic chemicals should be checked for surrogate recovery. Laboratory blanks should also be analyzed to check for the presence of potential laboratory contaminants.

- Data Variability - Detection of hot spots is generally not the objective of the sampling program under a PA/SI or RFA. The number of samples required to represent the level of contamination with a predetermined level of confidence will depend on the uniformity or homogeneity of the contamination. This information can only be obtained via previous sampling events.

D.4.2 Baseline Ecological Risk Assessment; RI and RFI

This section focuses on HTRW data scoping (data needs and DQOs) for a detailed site investigation phase under CERCLA or RCRA. The detailed site investigation phase under RCRA is known as a RFI/CMS and under CERCLA as a RI/FS. Other HTRW site investigations are expected to be functionally equivalent, for example, for BRAC; for permitting of an onsite hazardous waste incinerator (RCRA Subtitle C, Subpart 0); for miscellaneous units (RCRA Subtitle C, Subpart X): or for pertinent land disposal units (RCRA Subtitle C, Subparts J, K, and L). The site investigation execution phase for CERCLA and RCRA is generally known as a Phase II execution project phase.

D.4.2.1 Background Information Review

By a Phase II execution project stage, the risk assessor and the project team should have some understanding of the site background and descriptions of site characteristics from a review of the preliminary (PA/SI or RFA) data contained in the Federal Facility Docket or pertinent project files. At certain sites, removal actions, risk screening/exposure pathway analysis, or HRS scoring may have been performed. This information will be useful in scoping the data needs for a baseline ERA. Before the site strategy for the Phase II execution project phase is developed or revised, it is recommended that the project team carefully review the TM memorandum (or its updates), all site background information, file searches, and other relevant information concerning site ecological resources, habitats, and the receptors of concern.

The data collection approach and quality requirement should address concerns expressed in the NPL or the RFA report/permit requirements. The site strategy plan should be revisited and the need for additional data to support PDs examined.

The background information review should focus on the following issues:

- Regulatory concerns or site problems (or newly identified concerns) relating to: receptors, COECs (e.g., ecotoxicity, BAF, BCF), stressors of concern, and exposure pathways of concern.

- Project status with respect to the decision path leading to site closeout.

- Customer's or PM's goals and objectives, plan of actions, compliance requirements, and budget/ time constraints for the detailed site investigation and later project phases.

D.4.2.2 PDs

Broadly defined decision steps relating to detailed site investigations in CERCLA and RCRA within the critical path of the HTRW response program are:

- RI -- Upon completion of the RI or the RI/FS (if the FS is conducted simultaneously with the RI) and signing of the Super-fund Records of Decision (ROD), the critical decision step will be either the elimination of all or certain OUs/ AOCs from the next phase of the project, (i.e., no RD/RA needed based on the baseline ERA and compliance with ARARs) or a RD/RA is needed (for portions of the site or for the entire site) which proposes selected remedies to mitigate risks and comply with ARARs. The decision path also includes considerations for removal actions/interim actions and public

notice/participation on the proposed remedies or no action alternative.

- RFI -- Upon completion of the RFI, the critical decision step is likely to be either that (1) further study is required (i.e., corrective measure study) to define baseline risk and to propose remedial alternatives or (2) no further remedial action is required (i.e., compliance is achieved with respect to permit conditions or RCRA enforcement actions) based on comparison with proposed action levels, ARARs, or benchmark values. If the baseline risk assessment indicates unacceptable risks, corrective measures (selected remedial alternatives) will need to be implemented. The decision path also includes considerations for removal actions/interim corrective measures.

There are many objectives for a RFI and RI. For example, a Phase II project executable stage identifies COECs, investigates the amount of release and the nature/extent of media contamination, evaluates the fate and transport properties of CORCs and affected media, assesses baseline risks, determines the opportunities for removal actions or interim corrective measures/early actions, assesses and recommends remedial alternatives to mitigate risks, and documents investigation and response actions. Generally, if there is no appreciable evidence of release or if the baseline ecological risk is acceptable (determined either through a baseline risk assessment or a comparison with ecologically concern levels or benchmark levels), there should be little basis for a FS, CMS, RD/RA, or a CMI. If contamination is found at the site (onsite, offsite, or at multiple locations) and ecological receptors could co-occur with this contamination spatially or temporally (e.g., during the early life cycle in the species natural history), a site-specific baseline risk assessment will be needed to ascertain if:

- Further investigation (e.g., to address hot spots) is warranted with or without removal actions.
- Immediate or emergency response actions to mitigate short-term risks are needed.
- Remedial alternatives/corrective measures should be implemented to mitigate site risks.

Therefore, specific project decisions (PDs) associated with a Phase II executable project phase are:

- Determine if the "site," SWMU, AOC, and, more appropriately, the EU, pose significant risk to the environment to warrant remediation or corrective measure.
- Determine if removal actions/interim corrective measures are needed to mitigate imminent threat to the environment.

D.4.2.3 Project Study Elements

The project study elements for a Phase II project execution stage are concerned with defining the site nature and extent of contamination (including establishment of background or reference chemical concentrations to meet PD requirements): establishing an understanding of the fate and transport mechanisms of chemicals based on the findings of a site characterization element; and conducting a baseline ERA (based on the site characterization, fate/transport findings, site features, hazard [ecotoxicity or stress] and exposure information). For a Phase II project execution phase, data may be needed for all or any one of the following project study elements (including the baseline ERA) to respond to PDs of whether or not there is a need to undertake removal actions or remedial action/corrective measures. If a FS or CMS is to be performed after the RI or RFI, the project study elements must also support a decision of whether to go forward with the FS or CMS based on significant adverse impact (or risk) to the ecological receptors of concern or to valued resources. Potential study elements for a Phase II project execution phase are identified as follows:

- Evaluate the basis or need for emergency response or nonemergency (nontime critical) removal actions based on frequency, duration, and intensity of hazard, and the magnitude of response.
- Evaluate if potential removal options are protective.
- Identify and assess if SWMUs and OUs should be combined into CAMUs or AOCs for future remediation (if the ecological species or resources are spatially co-located with the units or areas requiring remedial action or corrective measure, the impact of these actions should be assessed as one single exposure unit [e.g., where the impacts of excavation/disposal or treatment permanently alter or destroy the landscape, available food sources, and habitats of ecological species of concern whose home ranges are within the remediated area]).

- Determine whether remedial actions are needed or no action is required for the entire site or portions of the site based on an assessment of the spatial and temporal distributions between the ecological receptors and the COECs. the baseline ERA in the impact area, and the fate and transport properties of COECs in the transport media.

- Provide justification or a basis to allow expeditious development of a FOST for a BRAC site which is also on the NPL, so that uncontaminated areas of a DoD facility can be transferred, sold, or segregated from the contaminated area of the site for the planned land use or continuation/modification of current operations, i.e., data of sufficient quality and quantity are needed to delineate contaminated areas which pose unacceptable risk.

D.4.2.4 Conceptualizing and Defining Data Needs

This project execution phase (Phase II) is comprised of four data tiers. Successive tiers are progressively more expensive and time consuming, starting with an assessment of individual effects or abiotic levels in Tier I to the study of population and community structure (diversity, richness and abundance) and function (recycling of energy and nutrients, and biomass/standing crop production) in higher tiers. Physical and biological models and extensive field monitoring and model validation may be required for the higher tiers. This multiple-option system of structured data needs is designed to allow the risk assessor and the project team members to economize data needs and to evaluate ecological risk cost-effectively. If data from the lower tiers ate deemed to be inadequate by the customers and regulators for decision-making, a higher tier may be pursued, if such studies or tests provide sufficient cause-effect relationships, associations, or inferences between the measurement endpoints (field or laboratory measurements/observations) and the assessment endpoints (species or resources to be protected). Generally, most HTRW projects with ecological concerns need only employ Tier I or Tier II data-gathering activities to satisfy site decision needs.

It should be noted that data needs at this stage of the HTRW project planning should focus primarily on the question: "What is the nature and extent of contamination and does the contamination co-occur with the spatial/ temporal distribution of ecological receptors?" If the answer is positive, the risk assessor's responsibility as the project team member should be to assist the customer and PM to decide the locations and media requiring removal or remediation based on the risk screening performed in the PA/SI or RFA, or the baseline ERA to be performed. Guided by the ECSM (established in the Phase I and refined if necessary in the Phase II project execution phases), data may be needed for all or any one of the following risk assessment/evaluation tasks to respond to the Phase II project execution phase PDs:

- Determination of current and future land use (including conversion of land to park and wildlife refuge) and the societal value of the resources to be protected.

- Fate and transport modeling of COECs in groundwater, air, and/or sediment (where applicable, [data needs may include pH, hardness, total suspended solids, precipitation rates, infiltration rates, aquifer thickness, hydraulic conductivity, total organic carbon, grain size, acid volatile sulfide concentration, bulk density, porosity, and processed meteorological data]).

- Collection of abiotic (exposure media) data including the nature and extent of contamination and biotic data to support the assessment of potential receptors and populations.

The site strategy and PDs developed under Phase I of the HTRW project planning process (Develop Project Strategy) for a RFI and RI will be the focus of this data scoping activity. Data needs may be nonchemical in nature, e.g., availability of food sources for indigenous species, land use planning/zoning maps published by the local government, regional geologic or hydrologic reports pub lished by the State or the USGS, Census or other survey reports or fact sheets, NOAA reports, or any other information that can be used to establish site characteristics, the existence of potential exposure pathways, receptors, or likelihood of exposure. Although some of this information may have been gathered in the PA/SI or RFA project execution stage, this information should be made as complete and as accurate as possible in order to prepare a defensible baseline ERA. Additionally, data needs may be chemical in nature, i.e., constituent concentrations in the exposure media (air, groundwater, soils, sediments, or surface water).

The output of this data scoping activity will be Data Needs Worksheets for this project execution phase (and subsequent project execution phases, if appropriate).

D.4.2.5 Define Data Types and Preferred Data Quality Requirements

This Phase II HTRW data-scoping activity eventually defines the data type according to potential exposure pathways. The ECSM is used to organize data needs and their relationships to PDs. Examples of data types, according to medium, for use in assessing potential ecological exposure pathways are: soil and surface-water ingestion, ingestion of food chain products/prey species, inhalation of airborne contaminants, and direct contact with the contaminated media. In each of these data types, monitoring data or data for modeling the exposure point contaminant concentration in the media are needed.

The risk assessor prepares Data Needs Worksheets for each pathway, documenting data types, quality requirements, or needs. Chemical data to be collected should be identified with QA/QC requirements. Customer's appropriate requirements for data quality, e.g., USACHPPM's data validation guidelines, should be followed In addition, the level of confidence (maximum error rate) required of the sample results should be set, after considering the potential variability of the sample results in a given matrix and potential laboratory/sampling handling errors. For nonchemical types of data, the QA requirements will be established and data can be obtained on a case-by-case basis. At a minimum, the source of nonchemical data and an assessment of their uncertainties, particularly reliability and representativeness, for use in demonstrating, correlating, or inferring ecological risk at the site should be documented." *See Rapid Bioassessment Protocols for Use in Streams and Rivers: Benthic Macroinvertebrates and Fish* (EPA 1989j) *and Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference* (EPA 1989c).

The level of confidence in the chemical data is dependent on the experience and expertise of the laboratory to deliver quality data QA/QC control, sampling method, sampling handling/preservation methods, and variability of the chemical concentrations in the medium sampled. Coordination between the risk assessor and chemist/data reviewer is recommended in order to design a sample collection program which is most likely to produce sample results with an acceptable level of confidence, considering such factors as laboratory QA/QC, level of QA required for the data, QA/QC samples, and data variability. Sensitive parameters should be identified in this scoping phase so that the site-specific data may be collected in a manner as to minimize the degree of uncertainty.

Typically, for the data types or parameters in a Phase II project execution stage, the data quality with respect to their identity should be good (i.e., QA3 or above), and the error rates should be relatively low (i.e., Type I error = 0.2 and Type II error = 0.1 or lower). An evaluation of data quality should examine the following five broad categories:

- Data Collection Objectives
- Documentation
- Analytical Methods/Quantitation Limits
- Data Quality Indicators
- Data Review/Validation

D.4.2.5.1 Data Collection Objectives. Data collection objectives should be examined as part of a data evaluation to determine whether the type and scope of analyses are appropriate for ERA purposes, and whether supportive information (such as QA/QC protocols) is available. Optimally, all data available for an ERA will have been collected with consideration of specific minimum requirements. These data should be evaluated in terms of the attainment of the objectives and the degree to which the minimum requirements were attained during sampling and analysis.

D.4.2.5.2 Documentation. The collection and analysis of site media should be adequately documented to demonstrate that the samples were collected, handled, and analyzed according to the DQOs and minimum requirements specified for ERA data, Documentation on adherence to these minimum requirements should be available for review by the risk assessor. Six types of documentation commonly developed for a site investigation are:

- Work Plan with DQOs. This plan scopes the extent of the site investigations and assessments and should identify the objectives for data collection and use.

[15] One of the key steps in establishing data quality and useability is the identification of reference area(s) which reflect background or local conditions unrelated to the site. Careful assessment and site visits and an early agreement with the regulatory agency are critical in order to address this issue effectively. The objective is to remove as many confounding factors as possible from the risk evaluation and to allow the ERA to go forward.

- SAP/Quality Assurance Project Plan (QAPP). This plan should specify the types and location of samples, the methods of sample collection, storage, and sample custody (i.e., tracking, shipping, and receipt), analytical procedures, and the level and type of QA/QC applied to the sample collection and analyses.

- Standard Operating Procedures (SOP). Provides consistency in the data collection, handling, and analytical procedures.

- Field Records. Field records document information on direct reading instruments, field conditions, some QA/QC protocols, and variations from SOPs or SAPs/QAPPs. Ecological observations made during abiotic media sample collection are an important component of the field records for the ERA.

- Chain-of-Custody Forms. Documents how the sample was handled (e.g., filtering, preservation, refrigeration) and the analyses requested, provides sample tracking, and documents receipt.

- Data Validation Report. These reports summarize the results of the data validation process and identify variations from protocol and qualifications to the data

Depending on the nature of the site and the preliminary Biota Checklist, a separate biological assessment document presenting more detailed ecological observations at the site may be required. Such assessments are typically required where threatened or endangered species are determined to be potentially present on the site.

After the data become available, the risk assessor should look for any deviations from designated protocols and evaluate their impact upon the data useability. Lack of documentation does not signify that the data are not useable, but it does limit the evaluation of data quality. Protocol deviations cause the uncertainty associated with use of the data to increase.

D.4.2.5.3 **Analytical** Methods **and Quantitation** Limits. The analytical methods applied to ERA data collection should be specified as part of the minimum requirements prior to the data collection. Three broad types of analyses are available (each having a different potential use in an ERA):

- Field screening data, such as those collected with direct-reading or field instruments (e.g., photoionization detectors, combustible gas indicators or field chemistry tests). Because of the uncertainty associated with these methods (due to lack of stringent QA/QC protocols) the data are best used only in a supportive role or used in conjunction with verified results from more reliable methods.

- Field laboratory analyses, such as those obtained from a mobile onsite laboratory.

- Fixed laboratory analyses.

Both the field and fixed laboratory analyses provide data appropriate for inclusion in an ERA if appropriate QA/QC procedures have been followed and the data are of good quality, as determined by the data validation process. In addition, several different laboratory analytical protocols are available, varying in the instrumentation, the level of QA/QC, sensitivity, quantitation limits and other factors. Appendix III of EPA's ***Guidance for Data Useability in Risk Assessment (Part A)*** (EPA 1992d) presents a summary of common analytical methods and identifies the instrumentation and detection/quantitation for different analytes. This resource should be consulted.

Two analytical protocols that are commonly applied to environmental samples are the EPA's Contract Laboratory Program (CLP) protocol and the SW-846 protocol. The analytical methods, quantitation limits, degree of QA/QC, and documentation differ between these two protocols. EPA's *Regulations on Test Procedures for the Analysis* of *Pollutants in Water* (40 CFR 136) should also be consulted.

Required quantitation limits should be low enough to enable detection of chemicals at concentrations of potential ecological concern. Quantitation limits are generally specified by the analytical method, however, deviations from planned quantitation limits can occur as a result of matrix interferences, high chemical concentrations, laboratory variations, and other factors. Therefore, the quantitation limits achieved in the analysis should be examined to evaluate whether deviations from the minimum requirements have occurred and whether those deviations have impacted the useability of the data.

The risk assessor needs to understand the type of quantitation limit associated with the analytical method and what is reported with the data. An understanding of the terminology is also needed. The term "'detection limit" is a general term that refers broadly to the concentration at which a chemical can be detected by a given analytical method. Although often used interchangeably, "detection** and "quantitation" are not synonymous. A detection limit is the lowest level of chemical in a sample that can be distinguished from the normal "noise" of an analytical instrument or method. A quantitation limit is the lowest level of a compound that can be accurately and reproducibly quantified. Compounds can be detected in a sample at concentrations too low to accurately quantify. Several different types of detection or quantitation limits are available. Each provides slightly different information on the sensitivity of the analysis and the meaning of analyzed data. These include the following:

- Instrument Detection Limit (IDL). The IDL is generally the lowest concentration of a chemical that can be detected by an instrument. This limit does not consider the analytical method, sample matrix, handling, or preparation factors.

- Method Detection Limit (MDL). The MDL represents the minimum concentration of a compound that can be detected by a specific analytical method and is generally higher than the IDL. This limit considers sample matrix, handling, and preparation factors. This estimate of a detection limit may be biased low, since it assumes 100% recovery of a compound by the analytical method.

- Sample Quantitation Limit (SQL). The SQL is a sample-specific limit that considers sample matrix, handling, and preparation factors. In addition, sample-specific adjustments (such as dilution) are considered.

- Contract-Required Quantitation/Detection Limits (CRQL and CRDL). The EPA's CLP specifies a CRQL for organic analyses and a CRDL for inorganic analyses. These limits are related to the SQL that has been shown to be routinely within the defined linear ranges of the required calibration procedures.

In general, SQLs are the most appropriate for use in an ERA, since they account for most of the variability in the sample preparation and analysis. For an ERA, the quantitation limits achieved in a data set should be sensitive enough to detect chemical concentrations associated with acceptable ecological risk and hazard levels. The appropriate quantitation limits can be determined a priori by performing a screening evaluation or using reference concentrations and unit risk levels.

D.4.2.5.4 Data Quality Indicators. Five data quality indicators need to be considered when reviewing chemical analytical results. These are:

- Completeness.
- Comparability.
- Representativeness.
- Precision.
- Accuracy.

The assigned data validator should examine these factors as part the formal data validation procedures. However, it is important for the risk assessor to understand the terms and their meaning in order to understand the data validation reports.

D.4.2.5.5 Data Review/Validation. Review and validation of chemical data can be performed at different levels and depths, depending on the desired use of the data. Prior to inclusion in an ERA, site data should undergo a validation process. Data validation should be performed by a chemist or other qualified individual. The risk assessor need only to know that the data have been reviewed or validated according to acceptable protocols, and all data have been appropriately qualified. Summary reports from the data validatom will inform the risk assessor of any variations or deviations from accepted protocols. The data review process should include an examination of the following factors:

- Evaluation of data completeness.
- Verification of chain-of-custody forms for correctness.
- Verification of instrument calibration.
- Measurement of laboratory precision using duplicates.
- Measurement of laboratory accuracy using spikes.

- Assessment of adherence to method specifications and quality control limits.
- Examination of holding times.
- Examination of blanks for contamination.
- Evaluation of the method performance in the sample matrix.

Different analytical protocols have different data validation requirements and may use different qualifiers or criteria for evaluating data. For example, USAEC uses different letter qualifiers to denote validation results than does the CLP. The risk assessor needs to be clear about who the audience is (e.g., NPL or State-led) and what are the appropriate validation requirements for the protocols used to ensure appropriate interpretation of the data.

At some point, the risk assessor may need to consider the precision and accuracy of the data validation protocol relative to the (anticipated) toxicity benchmark levels. For instance, when site media concentrations are orders of magnitude greater than benchmarks, a lesser degree of precision and accuracy is required. This would allow for use of a less stringent analytical protocol (i.e., Level 2 or 3 CLP, instead of Level 4).

D.4.2.6 An Outline or Summary of Approaches in the Risk Assessment/Risk Evaluation, Uncertainty Discussion and Recommendations

The approaches and contents of the anticipated baseline ERA should be explained or discussed in the project planning stage in unambiguous terms. The output of the discussion should be an outline or summary to be presented to the PM, customer, and other decision-makers, e.g., in the form of a technical memorandum which may be appended to the Work Plan to the agencies for approval. Since the ERA is conducted in a tiered approach, a decision diagram should be presented for discussion. The purpose of this documentation is to avoid potential misuse of the data or the risk assessment results, and can be used as a means to make sure that the selected data collection option meets the users' and decision-makers' needs. At this project planning phase, the customers, PM, data users, and decision-makers are provided the opportunity for comments on the approaches to analyze/assess risks and characterize/minimize uncertainties.

The EPA is site-specific, providing discussion and references to the potential exposure pathways presented in the ECSM. The exposure and risk characterization models should be highlighted in the outline/summary. In general, EPA-published models or peer-reviewed or validated models should be used to minimize uncertainty.

In explaining the data acquisition options, it is recommended that the risk assessor point out potential setbacks, problems, or difficulties that may be encountered in a "real world" situation. Although data are planned to meet DQOs, it is not unusual to receive data of various quality (confirmed by data validation) and quantity (data collection or analysis completeness check) due to unforeseeable circumstances or events in the field. For example, there may not be sufficient biological samples or species to be collected within the budgeted time period, and the targeted species may also be absent (despite early site reconnaissance which indicates their presence). Therefore, it is imperative that the risk assessor explain to the decision-makers early in the project planning stage approaches to conduct the baseline ERA and other risk evaluations. In particular, the risk assessor should explain the minimum data quality considered to be acceptable, how nondetects are treated, and how medium-specific data are evaluated or compiled to derive/model the exposure point concentration in the risk assessment.[16] The discussion should be based on the ECSM, focusing primarily on all potentially complete and significant pathways, and the weight-of-evidence approach to address uncertainties.

Uncertainties associated with the baseline ERA performed in a particular tier in this project phase should be explained and characterized to the extent possible. At a minimum, a discussion of the confounding factors and ways to eliminate these factors by a weight-of-evidence discussion is highly recommended. In recent years, the use of sensitivity analysis and Monte Carlo simulation has gained acceptance in characterizing uncertainties and propagation of risks. If Monte Carlo simulations are planned, the data (and their sources) used in the simulations should be defined in this phase of the HTRW project planning process. However, their use must be supervised by experienced ecotoxicologists and statisticians. The propagation of exposure and the exposure-response data could be demonstrated for a site with

[16] For example, if the FU data are skewed, it will be necessary to address site risk by separating the hot spot areas. The risk assessor may indicate this option in the Work Plan to further characterize hot spot areas without delaying the assessment of risks for the non-hot-spot areas.

exposure scenarios and ecotoxicity data involving multiple trophic levels.

The outline or summary should specify quality/quantity requirements, provide justifications for their use, and explain how they can be obtained. If semiquantitative risk assessment analysis is performed for the site, e.g., descriptive comparison of ecological attributes between the site and reference areas, the results should be presented with scientific logic and rationale: a weight-of-evidence approach is likely to increase the level of confidence of the conclusions or recommendations for the ERA performed in that specific tier.

D.4.3 Risk-Based Analysis of Remedial Alternatives; FS and CMS

The data-scoping requirements for the FS or CMS project execution phase focus on data to support a screening evaluation of all the potential remedial alternatives for their effectiveness to reduce the baseline site risk. Following the screening evaluation, a more detailed comparative evaluation of viable remedial alternatives (recommended options) for their risk-reduction capabilities is also conducted. The latter assesses any short-term risks to the environment, its recovery, and long-term residual risks. It should be noted that "no further action" is a remedial alternative to be evaluated. Many sites are required to have RI and FS or RFI and CMS conducted simultaneously. Therefore the preparatory steps for conceptualizing data needs for a RI/RFI or FS/CMS are comparable and will not be reiterated in this section.

D.4.3.1 Background Information Review

By this Phase III project execution phase, the risk assessor and the project team should have a good understanding of the nature and extent of contamination. In addition, they will also have a good understanding of the site strategy and customer's goals and concept of closeout. In reviewing the background information, the risk assessor should note the area of contamination requiring remediation or corrective action, and the location of these areas relative to sensitive environments and ecosystems to be protected. Existing ecological resource maps or GIS database for the region should be reviewed with respect to the proposed remediation areas, CAMUs, or OUs. Special considerations should be given to:

- Previous or newly identified regulatory concerns relating to residual risks (i.e., risk remaining upon completion of selected remedies and/or proposed removal actions), and the potential for recovery of altered or destroyed habitats.

- Options with respect to the decision path leading to site closeout and compliance if the selected alternative is not effective or fully implemented.

- Customer's goals and objectives, plan of actions, budget/time constraints for RD/RA, removal actions, and the 5-year review, if applicable.

D.4.3.2 PDs

The decision step within the critical path of the HTRW response program relating to detailed site investigations in CERCLA and RCRA are the same as those presented in Section D.4.2.2. The specific PDs are:

- Develop site-specific PRGs or alternative concentration limits (ACLs) for groundwater potentially impacting aquatic receptors, and set realistic and protective performance criteria (the remedial action objectives [RAOs]) based on the PRGs and other factors for the selected remedial alternative or measure.

- Screen remedial alternatives for protectiveness and their ability to meet RAOs while minimizing additional ecological risk or impacts from the implementation of the remedies.

- Determine if removal action(s)/interim corrective measures are needed to mitigate imminent threat to sensitive environments.

D.4.3.3 Project Study Elements

The essence of the project study elements in this project execution phase concerns developing site-specific PRGs, determination of RAOs, and screening remedial alternatives. In addition, considerations have to be given to the fate and transport mechanisms of any potential release or discharge of the media being remediated or stored, or of treatment effluents or byproducts, and the establishment of ECSMs for the potential remedial alternatives needing further evaluation. In addition to evaluating the remedial alternatives for "protectiveness" of the environment, the risk-based evaluation must consider the permanence of the risk and toxicity reduction, interruption of the exposure pathway(s) shown to pose the principal threat in the baseline ERA, and the post-remediation (residual) baseline risk. For example, dredging of toxic

sediment may produce limited or more permanent ecological harm, depending on the precautionary measures taken to minimize resuspension of toxic sediments. Therefore, the potential study elements are summarized and identified as follows:

- Develop PRGs or ACLs for consideration as target cleanup levels or RAOs to protect ecological species.

- Assess if RAOs are protective, given the acceptable risk range and uncertainties in deriving the PRGs or ACLs, background concentrations, and the analytical detection limits.

- Evaluate if risk reductions afforded by the proposed remedial alternatives are permanent and reliable, i.e., to assess if the selected remedies are protective after the implementation period (given the operational and maintenance requirements, treatability study data, and future site exposure conditions). For example, use of biomonitoring or sentinel systems to detect subtle changes or residual risks.

- Evaluate qualitatively or semiquantitatively if the selected remedial options which generate effluents, emissions, or residues (e.g., soil/sediment washing, low temperature thermal desorption, groundwater aeration system, and discharge of effluent to surface water body) during implementation pose short-term risks to terrestrial or aquatic ecological receptors onsite and offsite. If there are potential ecological risks, describe the magnitude and frequency/duration of the risks.

D.4.3.4 Conceptualizing and Defining Data Needs

Data needed for performance of the above project study elements should be based on the ECSM for the remedial alternative and the postremediation ECSM. Data relating to the design and operations, byproducts, and residues produced during and after remediation will be needed. These data types (chemical identity, emission rates, and concentrations) are needed to characterize the potential impact of the process waste stream, emissions, and residues. Due to schedule constraints, it should be noted that the quantitative assessment of short-term risk during remediation and recommendations for control measures may be conducted in the RD/RA or CMI stage.

D.4.3.5 Establish ECSMs

Two ECSMs are to be developed for each remedial alternative: (1) an ECSM during remediation or implementation of the corrective measure and (2) an ECSM for the site after remediation. The former is used to guide data needs to assess short-term risks, and the latter, to guide data needs for the degree of risk reduction or the post-remediation baseline risk. The exposure pathways of concern are primarily air (fugitive dusts from stabilization/earth work or volatile organic chemicals [VOCs] from an air stripper) and groundwater (e.g., discharge of treated effluent to the surface water bodies and the effectiveness of capture well systems to prevent offsite contaminant migration). It should be noted that neither of these evaluations require an assessment of the net environmental benefit if offsite treatment/disposal is an alternative to be evaluated. Therefore, the risk evaluations under a FS and CMS are limited only to impacts to ecological receptors onsite or near the facility. The ECSM determines the following information needs for this project execution phase:

- COECs.

- Potential target media

- Potential receptors in the target media.

- Major exposure routes, pathways, or mechanisms of stress and effects[17].

- Migration and transport potential of site chemicals from the source.

- Exposure areas or EUs.

- Potential secondary sources of contaminants, and their release/transport mechanism (if any).

[17] For example, deposition of fugitive dust or wetland sediments emanated from soil/sediment remediation adjacent to a stream could potentially cause physical as well as chemical changes in the streambed environment for benthic macroinvertebrates).

D.4.3.6 Define Data Needs

It should be noted that data needs at this stage of the HTRW project planning should focus primarily on the questions: "What is the cleanup goal or remediation action objective?; What is the degree of risk reduction offered by the remedial alternative or corrective measure?: Could removal or remedial action at the hot spots be sufficient to substantially mitigate site risk?; and What could be the potential short-term and long-term residual risks (and potential for recovery) associated with implementation of an alternative?"

Guided by the ECSMs, data may be needed for all or any one of the following risk assessment/evaluation tasks to respond to the PDs on whether or not a remedial alternative should be selected:

- Data to support fate and transport modeling calculations.
- Data to conduct qualitative and/or quantitative evaluation of uncertainties in the risk assessment (mean, maximum, minimum, or the entire distribution of values for key parameters identified by a sensitivity analysis).
- Data or information (from State natural resource agencies or local universities) on potentially exposed ecological receptors and populations nearby the site that could be impacted by the remedial action.
- Data to assess risk or hazard (rate, concentration, chemical identity, and toxicity) of emissions or treatment products/residues which may be released and exposed to ecological receptors.
- Representative and quality assured site media data or data on the treatment byproducts and residues.

All the above data may require pre-defined quality and quantity requirements. The risk assessor should coordinate with the PM/I'M and other data users (e.g., modeler, compliance/responsibility specialist, etc.) to acquire site-specific data to evaluate exposure, potential risk or adequacy/feasibility of a response action to protect the environment.

D.4.3.7 Define Data Types and Preferred Data Quality Requirements

This data-scoping activity eventually defines the data type according to potential exposure pathways (i.e., ingestion of and dermal contact with excavated soil/sediment, inhalation of airborne contaminants, etc.). The ECSMs are used to organize the data needs and their relationships to site decisions. Data Needs Worksheets for each pathway will be prepared to document data types, quality requirements, or needs. Chemical data to be collected should be identified with QA/QC requirements. In addition, the level of confidence (maximum error rate) required of the sample results should be set, after considering the potential variability of sample results in a given matrix and potential laboratory/sampling handling errors.

For nonchemical types of data, the QA requirements will be established and can be done on a case-by-case basis. At a minimum, the source of nonchemical data and an assessment of their reliability and representativeness for use at the site should be documented. Emission or discharge data may be modeled (e.g., sediment transport modeling) or estimated from performance test results of a full-size model or a pilot-scale model. Lessons learned or case studies using the same selected remedy or corrective measure should be reviewed for data comparability and applicability. The remedy-design engineer should be consulted to determine the appropriateness of certain treatability data before these data are requested for the risk assessment. The data quality may be lower, if it can be demonstrated that the technology or treatment method is judged to be effective from the engineering evaluation. It should be noted that in certain cases, creation of new habitats may be a viable option, and should be discussed with the expert ecologist(s) and/or the advisory panel (BTAG).

D.4.3.8 An Outline or Summary of Approaches In the Risk Assessment/Risk Evaluation

Like the baseline ERA (Phase II project execution phase), the approaches and contents of the risk-based evaluation of remedial alternatives should be explained or discussed in the project planning stage. The output of the discussion should be an outline or summary (e.g., in the form of a technical memorandum) to be presented to the PM,

customer, and other decision-makers. The purpose of the transmittal is to avoid potential misuse of data or the risk assessment results, and can be used as a means to make sure that the selected data collection option meets the users' and decision-makers' needs. At this data-scoping phase, it is imperative that other data users and the data implementors have the opportunity to review and comment on the data needs to avoid data overlaps or to identify alternative data sources. Where there is a convergence of risk reduction requirements for protecting human health and ecological species, the assessment approach and data needs for evaluating remedial alternatives to provide protection to both receptors should be presented. Where there is a divergent issue of risk reduction measures concerning the protection of human health and potential impact to the environment from the anticipated remedial alternative(s), the assessment procedures of such remedial options should also be clearly explained in terms of assessment uncertainties and choice of actions for the level of protectiveness for both receptors. Both issues should be concisely articulated in the summary or outline.

The ERA in this project execution phase provides a discussion of the potential exposure pathways presented in the ECSM. The exposure and risk characterization models should be highlighted in the outline/summary. In general, EPA-published assessment methods/models or validated models should be used. Risks to ecological receptors of concern or stress to sensitive environments (which may not necessarily be those selected for the RI or RFI phase) may be presented qualitatively or semiquantitatively . The uncertainty assessment for risk analysis under a FS or CMS may be characterized qualitatively. For evaluation of potential alternatives which may produce substantial off-gassing or effluent discharge, quantitative analysis of uncertainty may be accomplished by a sensitivity analysis or a Monte Carlo simulation. In either case, the ranges of values for sensitive parameters have to be known.

D.4.4 Short-Term Risks Associated with Construction; RD/RA, CMI, Removal Action, or Interim Corrective Measure

This section focuses on HTRW data scoping for the evaluation of risks posed by construction of CERCLA and RCRA removal or remedial actions (corrective measures) to endangered/sensitive ecological receptors or valued resources. This risk evaluation provides a more detailed evaluation of the selected remedial alternative (if such an evaluation has not already been performed in the FS or CMS), focusing on recommending options for designing measures to mitigate potential risks from the removal or remedial actions. To meet the risk assessment or evaluation data needs, the risk assessor should coordinate with the PM, TM, and other data users to identify the selected remedies which require risk evaluation in this project phase.

If a screening or comparative risk analysis has already been performed in the RFI/CMS or RI/FS project execution phase, performance of risk assessment tasks in this project phase is generally limited in scope unless there is a need for a more detailed risk assessment because the construction is likely to result in release of site COECs. If this is the case, information from previously performed risk analyses should be reviewed and additional data needs identified. The data needs for an ERA evaluating removal actions or remedial alternatives should generally follow the assessment framework described previously in this appendix, and should focus on identifying and addressing the sources of risks and uncertainty in the mitigating measures. When considering the data needs and their quality/quantity, consideration should be given for completing the evaluation in a timely manner. Striking a balance between the desire for site-specific/ treatability data and assumed data (data from other sites) for use in the evaluation is the key step in this project planning stage. Specifically, the evaluation addresses:

- Short-term impact of the remedial alternatives on site environment (ecological receptors).
- Magnitude, frequency, and duration of the exposure to the stressor (chemical and nonchemical entities).
- Potential chance and time required for a recovery, if applicable.

As with other sections, the scoping/planning of risk assessment in RD/RA presented in this section does not cover radioactive and biological substances.

Other areas for project planning that may require coordination between the risk assessor and other project team members (e.g., the project biologist or ecologist) am:

- Risk of accidental spills and releases from construction of the remedial alternative (i.e., physical hazards, explosions, spills, etc.) resulting in substantial harm to the sensitive environments.

- Risk communications (public perception and understanding of species or resources at risk from implementation of the alternatives).

- Other risk management considerations or criteria, e.g., cost, schedule, O&M/engineering and operational flexibilities, etc.

None of the above are the focus of this section, which addresses short-term risks to terrestrial ecological species from emanation of site chemicals during construction activities.

D.4.4.1 Background Information Review

By this project execution phase, the project team should have a thorough understanding of the site background and characteristics and the approximate boundary of contamination requiring removal or remedial action. With the latter, it may also be possible that removal actions or interim corrective measures have been taken at the site. In addition, a baseline ERA and a risk-based evaluation or justifications for selecting certain remedial alternatives or corrective measures should have been performed according to requirements for evaluation of remedial alternatives under CERCLA Section 121, NCP Section 300.430(e), or Subpart S of the proposed RCRA Corrective Action Rule. This information will be useful in conducting risk analyses to assess the impact to ecological receptors or valued resources qualitatively or quantitatively from the selected remedial alternatives or new/additional removal actions. Before conceptualizing data needs to assess the short-term risks, a site strategy is developed or revised, and it is recommended that the project team carefully review all site background information, and RI/FS reports, and any pertinent field tests or studies.

D.4.4.2 PDs

A good understanding of the agencies' regulatory processes and how the site strategy fits in the regulatory processes, i.e., the program objectives for a RD/RA or CMI, and removal action or interim corrective measure will be helpful to develop PDs. The decision steps for this project execution phase are:

- RD/RA -- Data obtained from the previous project will be used to design a full-scale remedial action plan or report (with specifications for the technology or process employed, and QA to be achieved) which is then issued to the remediation contractors for bid, implementation, and documentation. Upon completion of a RD/RA, the critical path will be either site closeout (site delisted from the NPL) or periodic monitoring with or without a 5-year review to assess residual risk and compliance with ARARs prior to site delisting. The decision path also includes considerations for removal actions prior to or during RA implementation.

- CMI -- The critical decision path is similar to the above CERCLA path. Upon completion of the remedial design phase, the selected corrective measures are implemented. After CMI, the critical path is likely to be either: (1) RCRA compliance status achieved or (2) periodic monitoring to verify compliance. For SWMUs associated with an active hazardous waste management facility, the RCRA corrective action compliance status may be reviewed at the time of the next Part B permit renewal.

- Removal Action or Interim Corrective Measure -- The action or corrective measures are designed to stabilize the site, i.e., control of contaminant migration or interruption of an exposure pathway which poses the principal threat at the site. Although in some cases, the removal action or interim corrective measure is the final site remedy, most sites will require further characterization and determination of remedial action(s). Therefore, the removal action or interim corrective measure should be complementary or consistent with the probable site remedy. Removal action or interim corrective measure can be implemented at any time between site discovery and site closeout.

Through qualitative or quantitative risk assessment or analyses, a determination will be made on whether or not additional controls are needed to address risks during remediation or to address the residual risks. If the current or earlier assessment conducted in the FS or CMS indicates potential risks, the project decisions will focus on determining: (1) whether the selected remedy can be effectively implemented, under the current design and operation plans, without posing an unacceptable short-term risk or residual risk; (2) the need for extraordinary measures (i.e., removal actions specifically targeted at hot spot areas) to reduce the threat of ecological risks or expedite/enhance site remediation; and (3) long-term control measures (operational or engineering) to mitigate site residual risks and to ensure compliance with ARARs, to-be-considered requirements, and permit conditions. Therefore, specific PDs associated with this executable

project phase may include all or any combination of the following:

- Determine whether the selected remedial or removal actions are likely to comply with Federal and State ARARs or with to-be-considered environmental criteria required by the agencies regarding short-term risks.

- Determine if additional control measures are to be designed and implemented for the selected remedies or measures to minimize short-term risks.[18]

- Determine if the selected removal actions/interim corrective measures are consistent with the final site remedy (if such a remedy is reasonably expected).

D.4.4.3 Project Study Elements

The following are potential project study elements associated with assessing short-term risks from construction of removal actions, interim corrective measures, remedial actions, or RCRA corrective measures.

- Evaluate the need for removal actions/interim measures to mitigate the environmental impacts, thereby facilitating implementation of the remedial action or corrective measure. The evaluation should be based on the ECSM developed in the FS or CMS phase when the remedial alternatives were screened and evaluated.

- Establish the fate and transport mechanisms of site media proposed for removal actions or interim corrective measures, e.g., sediment transport modeling.

- Conduct a detailed risk analysis of short-term risks posed by implementation of the removal action/interim corrective measure, and demonstrate that environmental injuries are not likely to occur (only applicable to sites with potential NRDA actions).

- Conduct a baseline risk assessment of the site after implementation of the removal action or interim corrective measure is completed to demonstrate that no further action or remediation is needed because of acceptable ecological risks. (Note: this assessment activity is performed in Phase I or II of the project execution stages).

D.4.4.4 Conceptualizing and Defining Data Needs

Data needed for detailed risk evaluation of the selected remedial alternatives or removal actions should be based on the ECSM, and focus on the potential impact of the remedy or corrective measure to identified receptors. A good understanding of the contaminant fate and transport mechanisms associated with the site action(s) is the key to the assessment. The data needed may be nonchemical in nature, e.g., engineering design parameter to reduce, remove, or change the physical/chemical nature of the emission, effluent discharge, or residues. The sources of these data may be the remediation vendors/contractor, EPA's literature (e.g., feasibility studies under the Superfund Innovative Technology Evaluation [SITE] program), or design information from other sites (lessons learned) using the same/similar technology and wastes. The data needed may also be chemical in nature, e.g., constituent concentrations in the emissions or discharge, or the chemical identify, toxicity information, quantity, rate of release, and fate and transport characteristics of treatment byproducts, derivatives, or residues. The potential changes in bioavailability or solubility due to chemical transformation of the turnover/resuspension media from anoxic to an oxygen-rich environment associated with removal or excavation action should also be assessed. Information concerning the areal extent of potential habitat destruction or alteration is also needed.

The site strategy and PDs developed under Phase I of the HTRW project planning process for this project planning phase, and revised under the Phase II process, will be used to focus data-scoping activities. The outputs of the

[18] It should be rare for the PM of a HTRW site to re-propose another remedial alternative if one has already been selected and entered into the ROD or permit modification. It is plausible that a selected remedy (indicated in a ROD signed a number of years ago) is no longer appropriate based on the new data. Notice of any new remedies will have to be published for public comment, and will require detailed explanations for the change. All of these activities will require additional time and effort.

Phase III technical project planning process are the Data Needs Worksheets for this project phase and, where appropriate, the documentation requirements for site delisting, compliance, or NRDA data collection requirements (40 CFR Part 11, Subtitle A).

D.4.4.5 Establish or Refine ECSM(s)

As additional chemical fate/transport and contaminated media release data are obtained or estimated, the ECSM established in the RFI/CMS or RI/FS project execution phase could be revised, as necessary, to provide a more detailed evaluation of a selected remedy or removal action. The ECSM developed in the previous project phase presents all potential exposure pathways and identifies those pathways which are complete (significant or insignificant) and incomplete under the baseline or no remedial action conditions. This ECSM should be appropriately modified to help the project team focus the data collection effort on evaluating significant pathways as potential emission or discharge sources during remediation.

If substantial waste constituents remain onsite, the residual risks can be assessed based on the baseline ECSM, as long as the waste sources/matrices, spatial relationship with respect to receptors, or the fate/transport properties are substantially unchanged. The ECSM will help address PDs. If multiple remediation actions are to be implemented simultaneously, multiple ECSMs should be developed for the OUs, SWMUs, AOCs, or CAMUs/TUs. The information requirements for development or revision of the ECSM(s) are the same as those described in preceding ECSM sections.

D.4.4.6 Define Data Needs

It should be noted that data needs at this stage of the HTRW project planning should primarily focus on the PD: "What is the short-term risk to the appropriate ecological receptors (individuals and community) or sensitive environments onsite and/or offsite?" For example, if the remedial action requires storage and dewatering of contaminated sediment, a confined disposal area will be required. If the disposal area is constructed onsite, the environmental risks from such a construction activity will need to be evaluated as the construction activity is part of the remedial action. (Note: Ocean disposal of dredged sediment is a permitted activity under Section 103 of the Marine Protection, Research, and Sanctuaries Act of 1972. Guidance for tiered testing of dredged sediment has been published jointly by the USACE and EPA (1991g). Therefore, data scoping discussed in this section does not apply to this particular situation.)

If potential environmental risks may occur, the risk assessor's responsibility as a project team member should be to identify for the customer and PM significant exposure pathways and risks. In this project planning phase, a close coordination between the risk assessor, chemists, modeler, design engineer, and legal-responsibility counselor will be needed to define data quality and quantity needs. The risk assessor may be required to coordinate with other data users (e.g., compliance specialist) to acquire additional site data to document QA compliance, and adequacy of response action to meet the RAOs and ARARs.

Guided by the ECSM, data may be needed for all or any one of the following risk assessment/evaluation tasks to respond to the PD on whether or not there is a need to impose control measure: augment or modify the selected remedy; or conduct removal actions:

- Confirm current and future land use and the environmental setting/characteristics. (If areas adjacent to the site to be remediated will be developed into industrial/commercial use, it is likely that the focus of the societal value of resources to be protected or the ecological receptors of concern will also change. This will need confirmation.)

- Identify mode of operations for single or multiple remedial actions and proximity of these actions to potential ecological receptors and their home ranges.

- Perform a risk assessment/analysis quantitatively or qualitatively, based on the revised ECSM, and present findings with a discussion on uncertainties; some of the data requirements for this may be:

  - Data to support fate and transport modeling/ calculation, e.g., grain size of soil or sediment handled, organic carbon content, oxygen level, river or stream contours, scouring depths, leaching characteristics, processed meteorological data, etc.

  - Data to assess the amount of discharge or residues, e.g, amount of soil resuspension for a specific soil/sediment handling method,

estimation of fugitive, volatilization, or stack gas&articulate emissions, effluent discharge rates, etc. (i.e., representative monitoring or field data to assess risks and demonstrate compliance with protective criteria/standards are needed).

- Data to support qualitative assessment of potential exposure to ecological receptor populations and communities (e.g., method of residue disposal or environmental media into which effluents/emissions are discharged, material handling and movements, associated support services that may impact sensitive environments [construction of access roads through wetlands or woodlands]).

- Data to assess risk or hazard (toxicity information of waste residues, byproducts, derivatives, and degradation products [for bioventing or bioremediation]). [19]

- To compare ARARs and to-be-considered short-term (acute) concern levels (e.g., LC_{50}, LD_{50}, and EC_{50}) with representative site sample or field monitoring data which meet predefined QA/QC criteria

D.4.4.7 Define Data Types and Preferred Data Quality Requirements

This HTRW Phase II data-scoping activity eventually defines the data types according to potential exposure pathways. The ECSM is used to organize the data needs and their relationships to site decisions. Examples of data types according to medium for use in assessing potential exposure pathways for ecological receptors are: incidental ingestion/dermal contact with the treatment residues or effluent and to a lesser significant degree, inhalation of airborne particles or volatilized organic chemicals. In each of these data types, sample or continuous monitoring data and data for modeling the exposure point concentration for the site contaminants or their treatment derivatives/residues in the media may be needed.

To evaluate the selected remedial alternatives under this project phase for their short-term impact during remediation and residual risk after remediation, data relating to the design, operation, and maintenance of the remediation system are needed to calculate the discharge or release rates of the site constituents and the process waste streams. Data required on the process waste streams include chemical characterization of all remediation or treatment byproducts, derivatives, or residues during and after remediation, which may impact onsite and offsite endangered/sensitive ecological receptors. It should be noted that the screening or comparative assessment of remedies may have been conducted in the RI/FS or the CMS stage. The data used in these screening or comparisons should be reviewed to see if they meet the data user's requirements for quality?'

Given the project constraints, the following considerations may be appropriate:

- A qualitative evaluation, based on data from the site or from comparable sites, to provide a screening evaluation of the selected remedy.

- A data collection program that is sufficient to make a defensible evaluation. For example, if air modeling/deposition has already been performed in the RI/FS and RFI/CMS stage, data collected such as the dispersion factor and deposition rates for certain constituents should be used in the detailed analysis of the selected remedy in this project phase.

- Although site-specific data are often preferted, such data may not be needed if the technologies or remedial actions pose risks to humans via the same exposure pathways or routes. In this case, a simple qualitative or quantitative comparison

[19] Bioremediation of groundwater should consider potential toxic degradation products, e.g. transformation of trichloroethylene (TCE) to vinyl chloride. The assessment of discharge of this treated or partially treated groundwater to surface water will require fate/transport data, e.g., half-lives of degradation products and their ecotoxicities.

[20] A focused effort (qualitative or quantitative) should be made in the evaluation of remedies. Offsite remedies or actions should not require evaluation, in most cases. Innovative technologies which produce treatment residues, emissions, or discharge should receive a detailed evaluation (e.g., quantitative evaluation), especially if the technologies have not undergone such an evaluation, using exposure conditions comparable to those at the HTRW site. The risk assessor and project team should leverage existing information or data for the type of remediation technologies considered to provide information for risk management decisions relating to the selected remedy. biomonitoring, and the need for 5-year review.

between the rates of discharge of emissions, based on the design criteria between the site being evaluated and a similar design which does not pose site risk, may be sufficient, unless the constituents and chemicals released are subject to very different degradation rates subsequent to release.

- Some data are more important or critical than others because of potential variability or the extreme conservatism inherent in one type of data versus another. For example, it will not be appropriate to assume the worst case meteorological conditions to express high concern or reject an onsite treatment technology under detailed analysis.

- Generally, the inhalation exposure pathway is a pathway of concern during an RA involving excavation or in situ treatment/removal (air stripping). However, unlike humans, any disturbances are likely to discourage wildlife in the remediation area. Data needs for assessing risks from inhalation are generally of lower priority than those for other pathways. However, the deposition of particulates or spills onto waterways and streams, impacting sensitive or endangered aquatic receptors, should not be ignored.

- Generally, surface-water ingestion and dermal contact are pathways of concern during remediation to aquatic species or wetland species. Leaching of postremediation groundwater would be a concern to assess for these species.

Suggested relevant EPA's guidance for review are:

- *Superfund Remedial Design and Remedial Action Guidance* (OSWER Directive 9355.0-4A) (EPA 1986d)

- *Superfund Selection of Remedy* (EPA 1987b)

- *National Oil and Hazardous Substances Pollution Contingency Plan* (55 FR 8660, March 8, 1990)

- *Guidance on Remedial Actions for Contaminated Groundwater at Superfund Sites* (EPA 19881)

- *AirlSuperfund National Technical Guidance Series (Volumes I through IV)* (EPA 1989h,i; 1992i; 1993d; 1995g)

- *Estimation* of *Air Impacts* for the *Excavation* of *Contaminated Soil* (EPA-450/1-92-004) (EPA 19920).

Some considerations for the quality assurance levels are as follows:

- For fate/transport modeling of air (and surface water, if appropriate) to assess short-term risks, EPA-approved model(s) and user's guidelines should be consulted with regard to data input quality. Most models are based on the conservation of mass, modified by chemical reactions, e.g. redox reaction or sorptive chemical equilibria with the transport medium, or decay. Therefore, the risk assessor and modeler should exercise care in applying models to make sure that the risk assessment results are realistic.

- For detailed evaluation of the potential health impacts associated with a specific remedy, site-specific modeling using representative site data (i.e., data from that particular region with similar meteorologic, topographic, or hydrologic characteristics) should be used.

- For chemical identification and quantification of concentrations, analytical data should be able to meet QA3 (Level 3) or higher quality. In other words, these data should be of a defined level of confidence, and reviewed for precision, accuracy, representativeness, comparability and completeness.

The risk assessor then prepares Data Needs Worksheets for each pathway, documenting data types, quality requirements, or needs. Chemical data to be collected should be identified with QA/QC requirements identified in the RI/FS and RFI/CMS SAP. If appropriate, the level of confidence required of the sample results may be set, after considering the potential variability of the treatability sample results for a given matrix and potential laboratory/ sampling handling errors. For nonchemical types of data, the quality assurance requirements will be established and can be done on a case-by-case basis. At a minimum, the source of nonchemical data and an assessment of their

reliability and representativeness for use at the site and implementation of the selected remedy should be documented. (It should be noted that large RD/RA or CMI projects are likely to require a demonstration pilot-scale study in the RD/RA project phase. The anticipated data needs for this project execution stage should be introduced in the QAPP or the demonstration plan for the RD/RA project phase, so that the study will provide the data needed for assessing short-term risks for the full remediation system[s]).

D.4.4.8 An Outline or Summary of Approaches In the Risk Assessment/Risk Evaluation. Uncertainty Discussion and Recommendations

The approaches and contents of the anticipated risk assessment/evaluation of selected remedial alternatives should be explained or discussed in the project planning stage in unambiguous terms. The output of the discussion should be an outline or summary to be presented to the design engineer, TM, PM, customer, and other decision-makers for discussion and coordination. The purpose of the transmittal is to provide ecological risk evaluation of the remedies specifically with respect to potentially complete exposure pathways and design needs in order to mitigate impact from identified pathways. The outline/ summary is also used as a means to ensure that the selected data collection option meets the users' and decision-makers' needs. At this project planning phase, the customers, PM, data users, and decision-makers are provided the opportunity for comments on the approaches to analyze/assess short-term and residual risks from the remedial action and to collect data, where needed, to reduce uncertainties.

The risk assessment evaluation should be site-specific, with discussion and references to the potential exposure pathways presented in the ECSM pertinent to the release of site constituents or process waste streams by the remedial action. The exposure and risk characterization models should be highlighted in the outline/summary. All exposure and risk models used should be clearly indicated and should be EPA-published models or peer-reviewed/ validated models. Generally, simple modeling and risk characterization methods like those applied in Phase I or under Tier I of Phase II of the HTRW technical project planning process would suffice. The outline/summary should indicate the appropriateness of all models and of combining risks across certain or all pathways. Since data of various qualities may be used (e.g., literature values, site treatability data, data from other site remediation, etc.), the outline should also explain the minimum data quality considered to be acceptable, how nondetects are treated, and how medium-specific data ate evaluated or compiled to derive/model the exposure point concentration in the risk assessment/evaluation.

Uncertainties associated with the risk assessment/analysis performed in this project phase should be characterized qualitatively. Quantitative assessment of uncertainties with the use of Monte Carlo simulations is generally not recommended unless the operational and design variables are highly uncertain and potential risks are to be evaluated based on set ranges of such variables. Nonetheless, the approach used in assessing uncertainties should be carefully thought out in this project planning phase. To minimize uncertainty associated with performance and chemical data needed to assess short-term risks, it is recommended that the risk assessor coordinate with the chemist/data reviewer and design engineer to plan the data collection program most likely to produce the required sample results with an acceptable level of confidence. Use of appropriate sampling methods, laboratory QA/QC, level of QA required for the data, and number of QA/QC samples will help to reduce chemical data uncertainty. To minimize uncertainty associated with the discharge/ emission rates, considerations should be given to obtaining realistic throughput and emission data based on engineer design or modifications of the selected technology, degree of destruction, treatment or ***removal,*** dust/ particulate generation rates, equipment type and soil type, where appropriate.

D.5 Summary Conclusions

Risk assessment or risk analysis is an important component of inputs into risk management or site decisions. Therefore, it is the goal that the assessment is performed with data of the highest quality and statistical confidence. Due to budget, schedule, and other project constraints, however, it is invariably not possible to obtain data of the highest quality at all times. This appendix presents an overview of the four-phased HTRW data quality design process, and a framework for conceptualizing and defining data needs and quality for scoping a risk assessment/risk analysis task for critical phases of the HTRW response action. The HTRW data quality design process emphasizes early planning and communications among data users (e.g., the risk assessor) and the data implementors (e.g., chemist and statistician) to develop cost-effective data collection program options for selection by the customer. The data collection program should be presented with a candid discussion of data limitations and benefits, the reasons why the data are needed, and how the collected data are to be used in site decision-making. This process is designed to increase the

customer's satisfaction because the selected data collection option is the result of team work with process improvement in the conceptualization, development, and refinement of the data collection program.

In scoping risk assessment data needs under Phase II of this data quality design process, the risk assessment follows a five-step procedure recommended by the process. The five-step procedure entails:

- Review Background Information.
- Assemble Project Decision Statements and Identify Study Elements.
- Conceptualize Data Needs.
- Define Data Needs and Group Data.
- Document Data Needs.

Section D.4 is devoted to establishing data needs under this five-step procedural framework for critical phase(s) of the HTRW response action. The HTRW response phases discussed include the PA/SI and RFA - project execution stage: the RI and RFI/FS and CMS - project execution stage: and the RD/RA and CMI - project execution stage. The data needs for assessing short-term risks associated with removal actions or interim corrective measures are also addressed under a RD/RA and a CMI section since both assessments deal with short-term risks from construction. The above discussion on scoping data needs was not intended to be all-encompassing. Rather, it was intended to prompt the conceptualizing and defining of data needs for typical project study elements performed to provide inputs to PDs,

Due to site-specific conditions and requirements, the readers are encouraged to establish data needs based on the fivestep procedures and communicate such data needs early to the data implementors. The data users (risk assessor) should anticipate tradeoffs among data needs, data quality and quantity (which may impact confidence level) due to cost, budget, and other project constraints. The expected data uncertainty and limitations from the tradeoff should be documented in Phases III and IV of the data quality design process along with the associated DQG statements for the selected data collection option.